A Proposed System-Level Performance Modeling Framework for Service Industries with Access to Limited Data

by Sallamar Krystal Adonna Worrell


A Praxis submitted to

The Faculty of
The School of Engineering and Applied Science
of The George Washington University
in partial fulfillment of the requirements
for the degree of Doctor of Engineering

May 21, 2017

Praxis directed by

Thomas A. Mazzuchi
Professor of Engineering Management and Systems Engineering & of Decision Sciences

Shahram Sarkani
Professor of Engineering Management and Systems Engineering
The School of Engineering and Applied Science of The George Washington University certifies that Sallamar Krystal Adonna Worrell has passed the Final Examination for the degree of Doctor of Engineering as of February 17, 2017. This is the final and approved form of the dissertation.

A Proposed System-Level Performance Modeling Framework for Service Industries with Access to Limited Data

Sallamar Krystal Adonna Worrell

Praxis Research Committee:

Thomas Andrew Mazzuchi, Professor of Engineering Management and Systems Engineering & of Decision Sciences, Praxis Co-Director

Shahram Sarkani, Professor of Engineering Management and Systems Engineering, Praxis Co-Director

Afi Harrington, Principal, AKEA Consulting, LLC, Technical Advisor and Problem Owner
Dedication

This praxis is dedicated to my parents and fiancé. Thank you for your support and encouragement. You are as dedicated to my goals and ambitions as I am. Thank you for your reassurance when I felt like giving up, staying up late with me when I needed to complete assignments, your understanding when I was unavailable, and all the other things you do to let me know that you are, and will always be, my biggest supporters. Donna, Samuel, and Lavar, thank you for helping me realize another dream.
Acknowledgements

I would like to acknowledge my advisors, Drs. Sarkani and Mazzuchi, for their invaluable feedback and support. In addition, I would like to acknowledge Dr. Afi Harrington for her technical advice and guidance throughout my research and Dr. Lula Beatty for her editorial guidance.
Abstract of Praxis

A Proposed System-Level Performance Modeling Framework for Service Industries with Access to Limited Data

Business process optimization allows businesses to remain competitive by allowing management to observe, analyze, and improve the operations of the organization. Using data and related business insights developed through applied analytic disciplines to drive business process optimization allows for fact-based planning, decisions, execution, management, measurement, and learning. However, this luxury is not possible for all; terms such as efficient, proactive, and effective are not generally used to describe the service industry, especially regulatory agencies.

This analysis aims to provide a framework that leverages the data that is readily accessible in service industries to quickly make insightful decisions, despite their data limitations. The proposed framework uses system dynamics, discrete event simulation, and queuing theory to provide a system-level data-driven strategy that can be utilized to identify bottlenecks in the current processes of service industries, serve as an aid to help management visualize where process hindrances are occurring, and assist management in investigating solutions that improve process efficiency. Publicly available data from the medical product review centers within the Food and Drug Administration was used to successfully illustrate the framework.

Keywords: process improvement, simulation, optimization, performance analysis
Table of Contents

Dedication ........................................................................................................................ iv

Acknowledgements .......................................................................................................... v

Abstract ........................................................................................................................... vi

Table of Contents .......................................................................................................... vii

List of Figures ................................................................................................................. ix

List of Tables .................................................................................................................... x

List of Symbols ............................................................................................................... xi

Chapter 1. Introduction .................................................................................................. 1

1.1 Problem Description ........................................................................................... 3

1.2 Solution Approach and Significance .................................................................. 6

1.3 Organization of Chapters ................................................................................... 7

Chapter 2. Literature Review ....................................................................................... 8

2.1 Process Optimization Strategies for Service Industries ..................................... 8

2.2 System Dynamics, Discrete Event Simulation, & Queuing Theory ................ 13

2.3 Case Study Background Information ............................................................... 23

Chapter 3. Research Methodology .............................................................................. 27

3.1 Research Objective ........................................................................................... 28
3.2 Research Questions .......................................................................................... 29

3.3 Hypotheses ....................................................................................................... 29

Chapter 4. Framework Methodology .......................................................................... 32

4.1 Framework Phase I: System-Level Process Model Creation ........................... 34

4.2 Framework Phase II: Microscopic Process Evaluation ................................. 38

4.3 Framework Phase III: Solution Engineering .................................................... 41

4.4 Framework Assumptions and Limitations in Scope ....................................... 43

Chapter 5. Results ..................................................................................................... 44

5.1 Phase I: System-Level Process Model Creation .............................................. 44

5.2 Phase II: Microscopic Process Evaluation ...................................................... 62

5.3 Phase III: Solution Engineering ....................................................................... 77

Chapter 6. Conclusions and Future Research ......................................................... 81

References ................................................................................................................. 84
List of Figures

Figure 2-1: System Dynamics Model Example ......................................................... 16
Figure 2-2: System Dynamics Feedback Loop for Growth Systems ....................... 17
Figure 2-3: System Behavior for Growth Feedback Loops ...................................... 18
Figure 2-4: System Dynamics Feedback Loop for Decay Systems ......................... 18
Figure 2-5: System Behavior for Decay Feedback Loops ........................................ 19
Figure 2-6: Feedback Loop and System Behavior for Constrained Growth Models ...... 20
Figure 2-7: System Dynamics Feedback Loop for Goal Seeking Systems ............... 21
Figure 2-8: System Behavior Examples for Goal Seeking Feedback Loops ............... 21
Figure 4-1: Framework for System-Level Optimization of Performance within Service Industries with Limited Data ................................................................. 34
Figure 4-2: Framework Phase I: System-Level Process Model Creation ................... 37
Figure 4-3: Framework Phase II: Microscopic Process Evaluation ......................... 40
Figure 4-4: Framework Phase III: Solution Engineering ......................................... 42
Figure 5-1: Organization Process Map for FDA Medical Product Centers ............... 46
Figure 5-2: PDUFA Simulation Results for Ten Year Run ..................................... 51
Figure 5-3: PDUFA Simulation Results for 100 Year Run ..................................... 52
Figure 5-4: MDUFA Simulation Results for Ten Year Run ..................................... 54
Figure 5-5: MDUFA Simulation Results for 100 Year Run ..................................... 55
Figure 5-6: GDUFA Simulation Results for Ten Year Run ..................................... 57
Figure 5-7: GDUFA Simulation Results for 100 Year Run ..................................... 58
Figure 5-8: BsUFA Simulation Results for Ten Year Run ..................................... 60
Figure 5-9: BsUFA Simulation Results for 100 Year Run ..................................... 61
List of Tables

Table 2-1: System Dynamics and Discrete Event Simulation Model Comparison ........ 14

Table 5-1: Framework Data Sources .............................................................................. 47

Table 5-2: Microscopic Process Evaluation Results for PDUFA ..................................... 64

Table 5-3: Microscopic Process Evaluation Results for MDUFA .................................... 71

Table 5-4: Required Number of FTEs to Sustain PDUFA and MDUFA Demand .......... 78

Table 5-5: Required Yearly Staffing Level Averages for User Fee Utilization Optimization .......................................................... 80
List of Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>variable being computed</td>
</tr>
<tr>
<td>C</td>
<td>correction</td>
</tr>
<tr>
<td>D</td>
<td>discrepancy</td>
</tr>
<tr>
<td>$\frac{d}{dt}$</td>
<td>the rate a given variable changes over time</td>
</tr>
<tr>
<td>g</td>
<td>gain</td>
</tr>
<tr>
<td>G</td>
<td>goal</td>
</tr>
<tr>
<td>I</td>
<td>sequence number</td>
</tr>
<tr>
<td>P</td>
<td>capacity</td>
</tr>
<tr>
<td>Q</td>
<td>system-level process map</td>
</tr>
<tr>
<td>R</td>
<td>rate of growth or decay</td>
</tr>
<tr>
<td>R (t)</td>
<td>growth rate with respect to time</td>
</tr>
<tr>
<td>S (t)</td>
<td>slowing action over time</td>
</tr>
<tr>
<td>T</td>
<td>time</td>
</tr>
<tr>
<td>U</td>
<td>bottlenecks within the process</td>
</tr>
<tr>
<td>V</td>
<td>system-level process</td>
</tr>
<tr>
<td>W</td>
<td>finding from the simulated model</td>
</tr>
<tr>
<td>X</td>
<td>current system state</td>
</tr>
<tr>
<td>X(0)</td>
<td>system state when time equals zero</td>
</tr>
<tr>
<td>X(t)</td>
<td>system state when time equals t</td>
</tr>
<tr>
<td>y</td>
<td>derived insights from the simulated model(s)</td>
</tr>
<tr>
<td>$\beta$</td>
<td>mean time between events</td>
</tr>
<tr>
<td>$\lambda$</td>
<td>mean event frequency</td>
</tr>
</tbody>
</table>
Business process optimization (also termed as business process redesign or business process engineering) allows businesses to remain competitive by permitting management to observe, analyze, and improve the operations of the organization (Davenport and Short 1990). Though all businesses can benefit from “the critical analysis and radical redesign of existing business processes to achieve breakthrough improvements in performance measures” (Teng, Grover, and Fiedler 1994, 10), process optimization is generally only exercised in the private sector where profitability is a great concern. Contrastingly, terms such as efficiency, proactive, and effective are not generally used to describe the service industry, especially regulatory agencies (Mihaiu, Opreana, and Cristescu 2010). This can be attributed to the notion that these administrations are not directly funded by the market. This makes them less exposed to the revenue loss due to inefficiency. They are also less motivated to reduce expenses and improve their operating efficiency, unlike their privately owned counterparts that need to vigorously compete for revenue (Rainey, Backoff, and Levine 1976).

However, there has been momentum for service organizations to become more transparent, proactive, and cost effective in recent years. For example, the United Kingdom has implemented several plans to decrease waste with regards to bureaucracy and over-government (Rinaldi, Montanari, and Bottani 2015) and introduced a new public management direction that exhibits principles of efficiency, effectiveness, and economy within the government infrastructure (Thomson 1992, Hood 1991, 1995, Pollitt 1993). In the United States, the National Performance Review was initiated in 1993 to
examine federal agencies and identify problems (along with proposed solutions) regarding operational costs; the committee was also instructed to look at issues that cut across agencies (Thompson 2000). More recently, President Obama signed the Digital Accountability and Transparency Act of 2014 into law on May 9, 2014. The legislation calls for the standardization of spending information and free public access to these reports; “by standardizing their spending information, inspector generals will be able to deploy anti-fraud analytics more cheaply and agencies will gain new enterprise-wide visibility into their accounts, obligations, and awards” (Data Coalition 2016).

Expanding beyond the financial realm, public administrations would greatly benefit from adopting a culture that embraces and promotes process optimization. Not only would these organizations be able to meet the mandates of the legislation above, they would inherently become more efficient and effective as they continuously reevaluate and improve upon their internal processes (Aversano et al. 2002). Federal agencies are constantly being mandated to implement new legislation regarding emerging technologies and/or services. Process optimization would help them to (1) understand their processes and resources at the current state (as well as the current resource shortages and surpluses), (2) be able to more accurately estimate the level of effort the new legislation would require, and (3) analyze process implementation strategy ideas to ensure a smooth transition when adding the new technology or services into the current work processes of the organization.

Additionally, the explosion of data storage and analysis technologies has made it possible to approach process optimization in a scientific manner. Data has become an invaluable asset to modern day organizations. The basis for a business’ competitive
advantage has shifted from the intuitions of senior leadership to the stories painted by data as companies leverage the advancements made in the computing and data storage industries. From tracking the comments of consumers on social media to leveraging the data that is created within their own organizations, management is turning to analytics to fuel their decisions and create favorable business positions for themselves within their respective industries.

1.1 Problem Description

As defined by MIT Sloan Management Review and SAS Institute Inc. in their 2014 research, analytics is the “use of data and related business insights developed through applied analytical disciplines (e.g., statistical, contextual, quantitative, predictive, cognitive and other models) to drive fact-based planning, decisions, execution, management, measurement and learning” (Kiron, Prentice, and Ferguson 2014, 6). This new analytics culture has exploded as companies invest vast amounts of resources into their information technology infrastructures to accommodate large volumes of data. However, this luxury is not possible for all.

Service industries provide the service of ensuring the consistency and/or efficacy of products provided to the public. These service entities are often faced with the difficult task of meeting their mandates with constrained resources. For this reason, it is imperative that the solutions they implement to improve their processes have a large impact on their efficiency, which explains why these agencies tend to implement proven information technologies and practices. However, this trend of technology adoption, as logically expected, has hindered the agencies’ ability to be proactive with respect to technological innovation. Furthermore, this retroactive cycle of technology adoption and
data collection increases the probability that the agencies will inadequately capture their workload and the essential processes needed for the efficient review of their regulated products. For example, the US Government Accountability Office (GAO) published a study (released in October 2015) that highlighted process inefficiencies within the Department of Veterans Affairs’. The report stated that the Department lacked a uniform process for treating patients and this variability caused wide expenditure differences between facilities in different regions; the analysts conducting the study stated that the large variances were most likely the result of inefficiencies in the care provided to patients (US Government Accountability Office 2015b). In another study (released in December 2015), GAO stated that the US Food and Drug Administration (FDA) “lacks reliable, readily accessible data on tracked safety issues and postmarket studies needed to meet certain postmarket safety reporting responsibilities and to conduct systematic oversight” (US Government Accountability Office 2015a). In the following month, GAO released another report that highlighted the process inefficiencies within the Centers for Medicare & Medicaid Services (CMS); in this report, they stated that CMS could not efficiently track their Care of Dual-Eligible Beneficiaries Program due to inconsistencies in the data from the participating states (US Government Accountability Office 2016b). These data oversights make it difficult to use analytics because the data simply does not exist.

However, there is a need for data analytics within these organizations. For example, GAO studied FDA operations (the report was released in May 2016) and found that the FDA’s strategic integrated management plans “do not describe a long-term strategy for addressing key issues that cut across medical product centers”, “do not describe the
agency’s plans for collaboration between the centers that could benefit certain initiatives, [do not describe the agency’s plan to] improve their decision-making, and improve the quality of evidence and clarity of guidance”, and “the absence of a comprehensive long-term plan for medical product oversight may hinder FDA’s efforts to address emerging issues that require center collaboration, such as access to quality data” (US Government Accountability Office 2016a). Though some agencies are actively working to improve their internal processes, like the FDA with their Center for Drug Evaluation and Research (CDER) Lean Process Improvement Initiative (Woodcock 2014), most of the investigated efforts are at the component level. This conventional analysis is necessary, but failure to look at the entire system hinders the agency from realizing the efficiencies that can be shared by implementing an agency-wide solution instead of lower level resolutions.

It should be noted, however, that the view of the system depends on the specific process one is analyzing; every process impacts the entire organization, but different components are impacted differently. Care should be taken to understand the organizational processes being considered to determine whether the entire organization should be considered the system or if the entity is a system of systems and a holistic observation of its processes need not include the entire organization. Furthermore, the system will depend on the type and completeness of data that is available for analysis.

There is a clear process for using analytics with the right data; the procedure, however, becomes problematic when there are limitations to the data (such as inadequate data or data that initially seems irrelevant). It is reasonable to assume that an organization, such as the FDA, is more likely to spend its resources meeting its
requirements (e.g. congressional reporting) than exploring the option of collecting data for process improvement. The question then becomes: *how do these organizations use the resources they have to reach the desired state of becoming data-driven?*

### 1.2 Solution Approach and Significance

This analysis aims to provide a framework that leverages the data that is readily accessible in service industries to quickly make insightful decisions despite their data limitations. The proposed framework uses system dynamics, discrete event simulation, and queuing theory to provide a system-level data-driven strategy that can be utilized to identify bottlenecks in the current processes of service industries, serve as an aid to help management visualize where process hindrances are occurring, and assist management in investigating solutions that improve process efficiency. The framework is fluid enough to handle large data discrepancies, yet comprehensive enough to create credible insights. The tools used are widely applicable and lucid, thus ensuring that the derived insights will be easy to interpret and transparent to all stakeholders involved in the data analytics process.

However, it should be noted that the absorptive capacity of an organization must be considered when selecting a process optimization framework. If an organization cannot effectively implement the insights discovered during the process optimization analysis, then the organization will remain inefficient (Manfreda et al. 2014). To ensure the fluidity of the framework, there are built-in steps within the proposed methodology to assess the “absorbability” of the proposed solutions generated by the model to increase the accepted solution’s probability of success.

To illustrate the framework, publicly available data from the FDA will be used. The
workload data from the medical product centers, along with their staffing levels, will be used as the framework inputs to describe the current state of the agency, identify bottlenecks within the current process, identify any interdependencies within the organization, and propose a long-term strategy for addressing key issues that cut across medical product centers in order to improve decision-making at the organizational level. The data publicly available is limited and provided on a snapshot basis, so rational assumptions will be needed in order to transpose the data to a level in which the analytical tools are valid and realistic.

### 1.3 Organization of Chapters

This praxis is organized by chapters. The following chapter titled “Chapter 2. Literature Review” provides the research to support the proposed methodology and background information for the case study. The subsequent section, “Chapter 3. Research Methodology”, explains the methodology behind the research presented in the praxis, as well as the research objective, questions, and hypotheses. “Chapter 4. Framework Methodology” describes the framework steps and assumptions. “Chapter 5. Results” uses user fee (Prescription Drug User Fee Act (PDUFA), Medical Device User Fee Amendments (MDUFA), Generic Drug User Fee Amendments (GDUFA), and Biosimilar User Fee Act (BsUFA)) data extracted from various FDA publicly available reports to illustrate how the framework is implemented. The final section, “Chapter 6. Conclusion” discusses ability of the proposed framework to meet the research objective, answer the research questions, and reject or accept the hypotheses; observed limitations and future research opportunities are also discussed.
Chapter 2. Literature Review

This section summarizes the research supporting the praxis methodology outlined in the following section. Additionally, relevant background information about the case study is also presented in this section. The material is divided into three categories: process optimization strategies for service industries; system dynamics, discrete event simulation, and queuing theory; and case study background information.

2.1 Process Optimization Strategies for Service Industries

Process optimization is an integral step in business operations and is synonymous with resilient corporate performance (Skrinjar, Bosilj-Vuksic, and Indihar-Stemberger 2008). It is needed to ensure quality, efficiently spend resources, and obtain a profitable state. Due to its importance, there are countless research articles about the importance of process improvement, but the approaches that should be implemented to achieve it are still in high demand (van der Aalst 2013). The paragraphs below outline some of the more recent works on process optimization methodologies that have been applied to service industries in chronological order. It should be noted that the aim of the proposed framework is to identify and analyze discrete actions that can be implemented by service organizations to radically improve work processes in a restricted timeframe. This undertaking is different from quality management, which aims to identify and implement initiatives to enable incremental improvement over an open-ended timeframe.

Yalley and Sekhon attempted to leverage the process improvement knowledge obtained in the successful manufacturing sector and apply it to the domain of service industries in January 2014. This literature review found that manufacturing productivity
assessment methods could not adequately be translated into the service sector due to the lack of productivity measures in service industries and well defined inputs, transformation processes, and outputs (Yalley and Sekhon 2014). While the manufacturing sector has established measurements of performance that are consistent from business to business, service sector organizations often have unique processes that can only be defined at an organizational level, if they can be defined at all (Yalley and Sekhon 2014). Agreeably, these findings are consistent with many papers; however, service industries arguably can be holistically described to have an input (reviewable submission), transformation process (review), and outputs (review decisions). Additionally, productivity measures, such as review times and compliance percentages of workload mandates, can also be defined and used.

During the winter of 2014, Manfreda, Kovacic, Štemberger, and Trkman illustrated in their research that an organization needs to assess its absorptive capacity prior to selecting a process improvement framework. By conducting a longitudinal case study of a public health insurance provider in Europe, they were able to determine that an organization with the best process improvement models at their disposal could still be unsuccessful at achieving a state of process efficiency because it does not have the ability to execute the plan into action and/or adapt to change (Manfreda et al. 2014).

TP, Rodrigues, Hebbar, and Backer proposed a methodology to improve the process of web development services in June 2014. Their process consisted of two major steps: (1) identifying methods to improve the web development process, (2) and implementing the identified methods into the website being built (TP et al. 2014). By first understanding the needs of the client (e.g. understanding their business and their desired
customer base), they would be able to identify the correct tools needed to increase the client’s website traffic and business opportunities (TP et al. 2014). The authors stated that identifying the client’s needs would provide the necessary inputs needed for search engine optimization and that the process can be further improved with the use of analytic tools such as Google web analytics (TP et al. 2014). Though this common sense framework proved to be very successful for the authors and uses simple tools that can be assessed by everyone, it is highly subjective based on the interpretation of the client’s needs.

In July 2014, Jones-Farmer, Woodall, Steiner, and Champ published research on the important considerations for understanding process variability, assessing process stability, estimating in-control process parameters, and selecting an appropriate in-control model. Though their research is specifically concerned with manufacturing data, some of the insights were applicable to the service sector. Their framework involved identifying the “key variables necessary to measure process quality” and using historical data to determine the distribution and the variability of the processes being observed (Jones-Farmer et al. 2014). This methodology is consistent with the notion of using the mandated workload outputs as the measures or process quality and using these historical figures to estimate the organization workload process of the service agency. The authors also concluded that rational subgrouping of the historical data is imperative to the process analysis and an appropriate method for rational grouping would be collecting data points that occur at the same time (Jones-Farmer et al. 2014).

In September 2014, Shrestha, Cater-Steel, Toleman, and Tam presented a paper that aimed to provide a clear guidance procedure for achieving process improvement in the
realm of information technology services. Instead of addressing all of the process inefficiencies, they proposed a multi-step method to identify the most critical inefficiencies using business drivers and service gap perceptions. Using the design science approach, they used the objectives of the proposed framework to determine the analysis tools that should be incorporated into the process improvement strategy (Shrestha et al. 2014). It was found that the balanced scorecard method would prove to be the most effective tool to weigh the process inefficiencies against the priorities of the key stakeholders and the business objectives of the organization (Shrestha et al. 2014). Additionally, the SERVQUAL model, a model frequently used to analyze service quality, was used to analyze the gap between consumer expectations and their perception of the service they actually received with respect to the inefficiencies being evaluated (Shrestha et al. 2014). The data provided by these two inputs was then used to construct a process selection matrix that management could use to select the most critical process inefficiencies to improve (Shrestha et al. 2014). Though this method did prove to be effective in the published case study, it is vulnerable to the biases of the entities providing the data. The inefficiency rankings may be estimated in terms of “gut feeling, plausibility considerations, or qualitative criteria”, thus making the framework findings inaccurate and unfeasible (Buhl et al. 2011).

In the same month, Bolsinger, Elsäßer, Helm, and Röglinger published a paper showing that a goal-oriented approach could be used to rank the operations performed in IT service industries. Their data driven approach assumes that the sequence of the operations within an organization is interchangeable, but each unique chain or operation has a certain cost associated with it (Bolsinger et al. 2015). To determine the optimal
sequence of operations, they use historical operations data and a process model as inputs to generate a map of all the sequence possibilities (Bolsinger et al. 2015). The map is then placed into a decision model to generate the most cost effective operation sequence based on a defined objective function (Bolsinger et al. 2015). This solution space reduction approach is one of the few instances in which data optimization is incorporated in a framework and used to achieve a feasible solution using historical data values without subjective data inputs.

Rinaldi, Montanari, and Bottani published a business process reengineering framework in September 2014 that uses data to provide a detailed representation of the current state of operations of an Italian public administration. Once the current state of operations was successfully mapped, they designed a business process reengineering simulation model to identify and investigate numerous “to be” models to evaluate achievable process improvements (Rinaldi, Montanari, and Bottani 2015). They found that the administration was overstaffed for its current workload (Rinaldi, Montanari, and Bottani 2015). However, their framework could not be generalized due to the specificity of its design to the organization used in the case study (Rinaldi, Montanari, and Bottani 2015).

In December 2014, Nesbit and Lam also published research on an organization’s absorptive capacity and process improvement. In their two-year longitudinal study, they analyzed the impact of an organization’s capacity to adapt to a change implemented at the organizational level (Nesbit and Lam 2014). Their findings showed that some small groups in management and the workforce were able to adapt to the implemented quality improvement initiative and embrace the change, however, there was little improvement to
the quality of the work products or culture on an organizational level (Nesbit and Lam 2014).

The framework proposed in this praxis builds on the literature presented above by providing a holistic view of the organization workload, not just a specific aspect of the organization. Additionally, the framework focuses on the interactions between the inputs and outputs of the system instead of the order of the processes occurring within the system. Aspects of the previous literature that will be adopted into the proposed framework are (1) describing service industries as entities with a defined input (reviewable submission), transformation process (review), and outputs (review decisions); (2) defining tangible productivity measures such as review times and compliance percentages of workload mandates; (3) assessing the organization’s absorptive capacity in order to evaluate the success of the proposed solutions; (4) using historical data and rational grouping to conduct optimization analysis; and (5) minimizing the use of subjective inputs.

2.2 System Dynamics, Discrete Event Simulation, & Queuing Theory

Simulation is an integral tool in understanding the processes of a system or organization. There are many variations of simulations in use today; the methods most commonly used are system dynamics, discrete event simulation, and agent based modeling (Maidstone 2012). Each of these techniques offers different perspectives when analyzing system behavior as it would be depicted in a real-world setting. The framework proposed in this praxis uses two of the previously mentioned techniques: system dynamics and discrete event simulation. These analysis tools will be used to observe and analyze the process model at a macroscopic and granular level. The third
simulation technique, agent based modeling, will not be included in the framework because the proposed framework in this praxis assumes that the service agency framework can be efficiently modeled as a queue. Since agent based modeling does not utilize queues, using this technique would be unreasoned (Siebers 2010). Furthermore, agent base modeling is more time consuming and complicated than the selected methods (Maidstone 2012), making it unsuitable for the proposed framework, since prompt analytical results and insights are desired. The table below illustrates the differences between system dynamics and discrete event simulation models (credit: (Tako and Robinson 2009)).

*Table 2-1: System Dynamics and Discrete Event Simulation Model Comparison (Tako and Robinson 2009)*

<table>
<thead>
<tr>
<th>Aspects Compared</th>
<th>Discrete Event Simulation</th>
<th>System Dynamics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nature of Problems Modeled</strong></td>
<td>Tactical/operational</td>
<td>Strategic</td>
</tr>
<tr>
<td><strong>Feedback Effects</strong></td>
<td>Models open loop structures – less interested in feedback</td>
<td>Models causal relationships and feedback effects</td>
</tr>
<tr>
<td><strong>System Representation</strong></td>
<td>Analytic view</td>
<td>Holistic view</td>
</tr>
<tr>
<td><strong>Complexity</strong></td>
<td>Narrow focus with great complexity &amp; detail</td>
<td>Wider focus, general &amp; abstract systems</td>
</tr>
<tr>
<td>Data Inputs</td>
<td>Quantitative based on concrete processes</td>
<td>Quantitative &amp; qualitative, use of anecdotal data</td>
</tr>
<tr>
<td>-------------</td>
<td>-----------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Randomness</td>
<td>Use of random variables (statistical distributions)</td>
<td>Stochastic features less often used (averages of variables)</td>
</tr>
<tr>
<td>Validation</td>
<td>Black-box approach</td>
<td>White-box approach</td>
</tr>
<tr>
<td>Model results</td>
<td>Provides statistically valid estimates of system performance</td>
<td>Provides a full picture (qualitative &amp; quantitative) of system performance</td>
</tr>
</tbody>
</table>

The system dynamics simulation technique allows for the system to be holistically modeled, showing the interactions between entities as well as the actions of each individual entity within the system over time. It depicts the behavior of the system being studied using flows, stocks, and delays. Maidstone defines flows as “the movement of items between different stocks in the system and out/into the system itself”, stocks as “basic stores of objects” and delays as a “delay between the system measuring something and then acting upon that measurement” (Maidstone 2012). One major advantage of system dynamics simulation technique is its ability to simplify the behavior of complex inter-related systems. Since this technique uses the flow of the system instead of focusing explicitly on the entities within the system, it proves to be an ideal tool for providing insights on how the system performs holistically and how it may be affected if modified. An example of a system dynamics model created in iThink is shown in (Campos-Náñez 2014a) below.
One of the key features of the system dynamics model is that it aids to conform the mental models of stakeholders (Sweetser 1999). Since stakeholders are likely to have different roles and interpretations of the process being modeled, they are likely to view the process differently. Furthermore, stakeholders may not have knowledge of the entire process, or view it differently, so they may have an incomplete or inaccurate view of the system that drives their function. Another key feature of the system dynamics model is that it uses a top-down approach to modeling, so it inherently needs to be endogenous, since the model cannot be presumed to be accurate if the entire system is not modeled (Sweetser 1999). Finally, the model composition determines the performance of the system. When the flows and interactions of the system entities are properly modeled, the feedback loops (structures that illustrate the important link between the entities within the system and the system as a whole (Sweetser 1999)) of the system can be identified and
insights may be obtained.

There are many feedback loop types for system dynamic models. Some of the more frequent model types are growth, decay, constrained growth, and goal seeking (Campos-Náñez 2014e). Growth feedback loops can model constant, geometric, exponential, or super exponential growth patterns (Campos-Náñez 2014d). The growth rates are proportional to the current state of the variable and follow the mathematical model below, where \( r \) is the rate of growth and \( X(t) \) is the function of the system with respect to time, \( t \).

\[
\frac{dX(t)}{dt} = r * X(t) \tag{2.1}
\]

Figure 2-2 illustrates its feedback loop for growth systems.

![Figure 2-2: System Dynamics Feedback Loop for Growth Systems (Campos-Náñez 2014d)](image)

The most commonly used growth model is the exponential growth model (Campos-Náñez 2014d). The solution to the generalized mathematical model is depicted below.
\[ X(t) = X(0)e^{rt} \]  \hspace{1cm} (2.2)

Additionally, Figure 2-3 shows growth system behavior over time, respectively.

![Figure 2-3: System Behavior for Growth Feedback Loops in System Dynamics Models](image)

Decay models are very similar to growth modes, but the rate is negative. The mathematical model of these systems is stated below.

\[
\frac{dX(t)}{dt} = -r \cdot X(t) \hspace{1cm} (2.3)
\]

Figure 2-4 illustrates its feedback loop for growth systems.

![Figure 2-4: System Dynamics Feedback Loop for Decay Systems (Campos-Náñez 2014b)](image)

The most commonly used model of this type is the exponential decay model (Campos-
Náñez 2014b). The solution to the generalized mathematical model is depicted below.

\[ X(t) = X(0)e^{-rt} \]  \hspace{1cm} (2.4)

Additionally, Figure 2-5 shows decay system behavior over time, respectively.

![Diagram of decay system behavior](image)

**Figure 2-5: System Behavior for Decay Feedback Loops in System Dynamics Models**

Similarly, models can exhibit the behavior of limited growth. These constrained growth models have two periods: growth and stagnation. These models are also known as S-shaped growth models and have a limiting factor that is outside of the system. The feedback loop and system behavior for this model type are depicted below.
The most common model of this type is the logistic growth model (Campos-Náñez 2014a) and it is mathematically illustrated below, where \( P, R(t) \) and \( S(t) \) are the capacity, growth rate and slowing rate, respectively, with respect to time.

\[
R(t) = r \cdot X(t) \\
S(t) = -\frac{r \cdot X(t)^2}{p} \\
\frac{dX(t)}{dt} = R(t) - S(t) = r\left(1 - \frac{X(t)}{P}\right)X(t)
\]  

Goal seeking behavior models are used to describe systems that self-correct themselves in order to reach a system state (goal) that is exogenous to the system (Campos-Náñez 2014c). In order to reach the goal state, the system must correct itself proportionally to the gap between the goal and the current system state. Mathematically, the correction, \( C \), discrepancy, \( D \), and system equations are modeled as follows (respectively) where \( g \) is the gain, \( G \) is the goal of the system, and \( X \) is the current state of the system:

\[
C = g \cdot D \\
D = G - X \\
\frac{dX(t)}{dt} = g(G - X(t))
\]
The two figures below illustrate the feedback loop and system behavior for these types of systems.

![System Dynamics Feedback Loop for Goal Seeking Systems](image1)

*Figure 2-7: System Dynamics Feedback Loop for Goal Seeking Systems (Campos-Náñez 2014c)*

![System Behavior Examples for Goal Seeking Feedback Loops in System Dynamics Models](image2)

*Figure 2-8: System Behavior Examples for Goal Seeking Feedback Loops in System Dynamics Models (Campos-Náñez 2014c)*

Similar to system dynamics models, the discrete event simulation technique can be used to model a system. While system dynamic models use stocks and flows to observe continuous changes in the system being observed, discrete event simulation models use a series of queues to observe changes within a system “as it evolves over time by a representation in which the state variables change instantaneously at separate points in time” (Law 2000, 6). Discrete event simulation can be used to replicate the performance
of an existing system and provide understandings on possible system modifications or proposals for similar systems, thus making this technique suitable for microscopic analyses for systems (Tako and Robinson 2009). Discrete event simulation models complement system dynamic models by providing statistically valid estimates of the system’s performance measures and bottlenecks within the system processes (Brailsford 2001). Unlike system dynamic models, there are no established mathematical formulas to use when defining the system. As a result, queuing theory and the collected historical system data will be used to define the behavior of the discrete event simulation presented in the following chapter.

Specifically, the framework adopts the assumptions that arrivals follow a Poisson distribution and the service times follow an exponential distribution (Adan and Resing 2015). Thus, Poisson and exponential random number generators will be used to model the system data times needed for the simulations. The Poisson random number generator will calculate a random sequence of numbers that follow the Poisson distribution. The mathematical equation for the Poisson probability distribution is illustrated below, where A is the variable being computed, i is the frequency in which an event occurs, and lambda (λ) is the mean of the data:

\[
P(A = i) = \frac{\lambda^i}{i!} e^{-\lambda}, \quad i = 0,1,2, \ldots
\]  

(2.11)

Similarly, the exponential random number generator will calculate a random sequence of numbers that follow the exponential distribution. The mathematical equation for the exponential probability distribution is illustrated below, where f(t) is the distribution of time between events and beta (β) is the mean of the data:
It should be noted that the parameter values of these distributions (lambda and beta, respectively) will be determined using the available system data.

2.3 Case Study Background Information

The US Food and Drug Administration (FDA) is an agency within the US Health and Human Services (U.S. Food and Drug Administration 2015b). It was established around 1848 under the US Department of Agriculture’s Division of Chemistry and was nothing more than a series of publications (U.S. Food and Drug Administration 2015h). Prior to 1906, the organization was focused on chemical analyses of agricultural products, but the passing of the Pure Food and Drugs Act, which prohibited the misbranding of food and drugs, began the transformation of the organization into what it is today. In 1938 the Food, Drug, and Cosmetic Act further increased the organization’s regulatory power over food and drugs, and is still the legislation under which the FDA continues to operate (U.S. Food and Drug Administration 2014i). Without the passing of this act, consumers would not be protected from misleading and/or unsafe food and drugs, such as blinding mascara, radioactive beverages, and elixirs with toxic solvents (U.S. Food and Drug Administration 2014i). Though the regulating law for the FDA is dated, the mission is not. The FDA’s primary objective is to provide the public with safe and effective food, drugs, devices, cosmetics, and radiation products as efficiently as possible (U.S. Food and Drug Administration 2015j). As stated on the FDA website, the organization is tasked with “protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation’s food
supply, cosmetics, and products that emit radiation” (U.S. Food and Drug Administration 2015j). The Agency is also responsible for “advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health”, “regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors”, and “ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats” (U.S. Food and Drug Administration 2015a). In order to accomplish these tasks, the organization must be efficient and effective with its technology adoption, business practices, and staffing structures.

The medical products regulated by the FDA, as stated on the FDA website, include:

- Drugs (prescription drugs (both brand-name and generic) and non-prescription (over-the-counter) drugs) (U.S. Food and Drug Administration 2016n)
- Biologics (vaccines, blood and blood products, cellular and gene therapy products, tissue and tissue products, and allergens) (U.S. Food and Drug Administration 2016n)
- Medical Devices (simple items like tongue depressors and bedpans, complex technologies such as heart pacemakers, dental devices, and surgical implants and prosthetics) (U.S. Food and Drug Administration 2016n)

Additionally, it should be mentioned that the FDA has created user fee programs to assist with the added cost of medical product regulation and the acceleration of industry innovation. These funds are used in conjunction with awarded congressional funds and
serve as distinct input parameters in the process model created in the case study chapter of this praxis. Below are the FDA provided descriptions of each of the user fee types.

PDUFA (U.S. Food and Drug Administration 2016d):

The Prescription Drug User Fee Act (PDUFA) was created by Congress in 1992 and authorizes FDA to collect fees from companies that produce certain human drug and biological products. Since the passage of PDUFA, user fees have played an important role in expediting the drug approval process. PDUFA must be reauthorized every five years, and was renewed in 1997 (PDUFA II), 2002 (PDUFA III), 2007 (PDUFA IV), and 2012 (PDUFA V). On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA), which includes the reauthorization of PDUFA through September 2017. PDUFA V will provide for the continued timely review of new drug and biologic license applications.

BsUFA (U.S. Food and Drug Administration 2016d):

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Biosimilar User Fee Act of 2012 (BsUFA), authorizes FDA to assess and collect fees for biosimilar biological products from October 2012 through September 2017. FDA dedicates these fees to expediting the review process for biosimilar biological products. Biosimilar biological products represent an important public health benefit, with the potential to offer life-saving or life-altering benefits at reduced cost to the patient. BsUFA facilitates the development of safe and effective biosimilar products for the American public.

GDUFA (U.S. Food and Drug Administration 2016l):

The Generic Drug User Fee Amendments of 2012 (GDUFA) is designed to speed access to safe and effective generic drugs to the public and reduce costs to industry. The law requires industry to pay user fees to supplement the costs of reviewing generic drug applications and inspecting facilities. Additional resources will enable the Agency to reduce a current backlog of pending applications, cut the average time required to review generic drug applications for safety, and increase risk-based inspections.

GDUFA is designed to build on the success of the Prescription Drug User Fee Act (PDUFA). Over the past 20 years, PDUFA has ensured a more predictable, consistent, and streamlined premarket program for industry and helped speed access to new, safe and effective prescription drugs for patients. GDUFA will also enhance global supply chain safety by requiring that generic drug facilities and sites around the world self-identify.

The current legislative authority for GDUFA expires at the end of September 2017. At that time, new legislation will be required for FDA to
continue to collect generic drug user fees for future fiscal years. More information on recent developments related to the reauthorization of GDUFA is available at the GDUFA Reauthorization Website.

MDUFA (U.S. Food and Drug Administration 2016m):

Device user fees were first established in 2002 by the Medical Device User Fee and Modernization Act (MDUFMA). User fees were renewed in 2007, with the Medical Device User Fee Amendments to the FDA Amendments Act (MDUFA II), and 2012 with the Medical Device User Fee Amendments to the FDA Safety and Innovation Act (MDUFA III). The FDA and representatives from the medical device industry and laboratory community have reached an agreement in principle on proposed recommendations for MDUFA IV. Once final, MDUFA IV will be in place from Oct. 1, 2017 until Sept. 30, 2022.

Under the user fee system, medical device companies pay fees to the FDA when they register their establishments and list their devices with the agency, whenever they submit an application or a notification to market a new medical device in the U.S. and for certain other types of submissions. These fees help the FDA increase the efficiency of regulatory processes with a goal of reducing the time it takes to bring safe and effective medical devices to the U.S. market.
Chapter 3. Research Methodology

The research in this praxis aims to create a holistic data-driven framework to identify and mitigate workload process inefficiencies within service industries with limited data. For the purposes of this research, limited data is defined as data that is not available or readily accessible. Service industries provide the service of ensuring the consistency and/or efficacy of products provided to the public. These service entities are often faced with the difficult task of meeting their mandates with constrained resources. For this reason, it is imperative that the solutions they implement to improve their processes have a large impact on their efficiency, which explains why these agencies tend to implement proven technologies and process models. However, this trend of languid adoption, as logically expected, has hindered the agencies’ ability to be proactive with respect to innovation. Furthermore, the retroactive cycle of technology adoption and data collection increases the probability that the agencies will inadequately capture their workload and the essential processes needed for the efficient review of their regulated products. For example, the US Government Accountability Office (GAO) recently stated in their December 2015 audit of the FDA that the agency “lacks reliable, readily accessible data on tracked safety issues and postmarket studies needed to meet certain postmarket safety reporting responsibilities and to conduct systematic oversight” (US Government Accountability Office 2015a). These data oversights make it difficult to optimize the processes within the organization because the data simply does not exist.

To the best of the author’s knowledge, and as deduced by the literature review chapter of this praxis, a holistic framework of this nature would be considered a novel
approach to the process optimization efforts within service industries, particularly service industries with limited data. The proposed framework builds on the literature presented above by providing a holistic view of the organization workload, not just a specific aspect of the organization. Additionally, the framework focuses on the interactions between the inputs and outputs of the system instead of the order of the processes occurring within the system. Aspects of the previous literature that will be adopted into the proposed framework are:

(1) describing service industries as entities with a defined input (reviewable submission), transformation process (review), and outputs (review decisions);
(2) defining tangible productivity measures such as review times and compliance percentages of workload mandates;
(3) assessing the organization’s absorptive capacity in order to evaluate the success of the proposed solutions;
(4) using historical data and rational grouping to conduct optimization analysis; and
(5) minimizing the use of subjective inputs.

It should be noted that the aim of the proposed framework is to identify and analyze discrete actions that can be implemented by service organizations to radically improve work processes in a restricted timeframe. This undertaking is different from quality management, which aims to identify and implement initiatives to enable incremental improvement over an open-ended timeframe.

3.1 Research Objective

The formal objective of this research is to produce a framework that enables service industries with limited data to holistically model, understand, and reform (if needed) their
organizational processes using the data that is readily available. The framework also promotes the development of process optimization insights that are cost effective, low in risk, and considerate of the absorptive capacity of the agency.

3.2 Research Questions

This praxis aims to answer the following research questions regarding the processes of service industries with limited data.

(1) Can a system-level process map that illustrates the known issues of a service agency with limited data be created?

(2) Can the bottlenecks of the system-level process be identified quickly using the process map?

(3) Can the identified system-level process be simulated to model the daily operations of the service agency?

(4) Can the bottlenecks be observed and pinpointed on a granular level (e.g. daily basis)?

(5) Can the findings from the simulation model be used to create process optimization insights that are cost effective, low in risk, and considerate to the absorptive capacity of the agency?

3.3 Hypotheses

The research questions stated above translate into the following research hypotheses.

\[ H_{10}: \exists q \in \mathbb{N} \]

\[ H_{10} : \exists q \in \mathbb{N} \quad (3.1) \]

H1a: A system-level process map, denoted as q, that illustrates the known issues of a service agency with limited data cannot be created.

H1a: A system-level process map, denoted as q, that illustrates the known issues
of a service agency with limited data can be created.

\[ H1_a: \quad \exists q \in \mathbb{N} \]  \hspace{1cm} (3.2)

H2_{0}: The bottlenecks of the system-level process, denoted as \( u_q \), cannot be
identified using the process map.

\[ H2_{0}: \quad \Sigma u_q = 0 \]  \hspace{1cm} (3.3)

H2_{a}: The bottlenecks of the system-level process, denoted as \( u_q \), can be
identified using the process map.

\[ H2_{a}: \quad \Sigma u_q > 0 \]  \hspace{1cm} (3.4)

H3_{0}: The identified system-level process, denoted as \( v \), cannot be simulated to
model the daily operations of the service agency.

\[ H3_{0}: \quad \not\exists v \in \mathbb{N} \]  \hspace{1cm} (3.5)

H3_{a}: The identified system-level process, denoted as \( v \), can be simulated to
model the daily operations of the service agency.

\[ H3_{a}: \quad \exists v \in \mathbb{N} \]  \hspace{1cm} (3.6)

H4_{0}: The bottlenecks, denoted as \( u_g \), cannot be observed and pinpointed on a
granular level.

\[ H4_{0}: \quad \Sigma u_g = 0 \]  \hspace{1cm} (3.7)

H4_{a}: The bottlenecks, denoted as \( u_g \), can be observed and pinpointed on a
granular level.

\[ H4_{a}: \quad \Sigma u_g > 0 \]  \hspace{1cm} (3.8)

H5_{0}: The findings from the simulation model, denoted as \( w \), cannot be used to
create process optimization insights, denoted as $y$, that are cost effective, low in risk, and considerate to the absorptive capacity of the agency.

$$H_{5_0}: \quad y \notin w \quad (3.9)$$

$H_{5_a}$: The findings from the simulation model, denoted as $w$, can be used to create process optimization insights, denoted as $y$, that are cost effective, low in risk, and considerate to the absorptive capacity of the agency.

$$H_{5_a}: \quad y \in w \quad (3.10)$$
Chapter 4. Framework Methodology

The framework illustrated below is the deliverable of this praxis. It uses system dynamics, discrete event simulation, and queuing theory to provide a system-level data-driven strategy that can be utilized to identify bottlenecks in the current processes of service industries with limited data, serve as an aid to help management visualize where process hindrances are occurring, and assist management in investigating solutions that ensure process equilibrium. The framework is fluid enough to handle large data discrepancies, yet comprehensive enough to create credible insights. The tools used are widely applicable and lucid, thus ensuring that the derived insights will be easy to interpret and transparent to all stakeholders involved in the data analytics process.

It should be noted that the absorptive capacity of an organization must be considered when selecting a process optimization framework. If an organization cannot effectively implement the insights discovered during the process optimization implementation, then the organization will remain inefficient (Manfreda et al. 2014). To ensure the fluidity of the framework, there are built-in steps within the proposed methodology to assess the “absorbability” of the proposed solutions generated by the model to increase the probability of the success of the accepted solution.

Publicly available data from the FDA will be used in the next chapter to illustrate the framework. The workload data from the medical product centers, along with their staffing levels, will be used as the framework input to describe the current state of the agency, identify bottlenecks within the current process, identify any interdependencies within the organization, and propose a long-term strategy for addressing key issues that
cut across medical product centers in order to improve decision-making at the organizational level.

The framework, illustrated in the figure on the next page, is divided into three phases. In the first phase, the process inefficiencies are identified, system data is assessed, and the system-level process model is developed. In the second phase, the data previously collected (including the process model) is used to create and simulate the organizational processes as a queuing model. The last phase uses the findings of the process optimization model created in the former phase to produce insights that are cost effective, low in risk, and considerate to the absorptive capacity of the agency. The phases are further elaborated below. Finally, the assumptions and the scope limitations of the framework are stated.
4.1 Framework Phase I: System-Level Process Model Creation

Phase I consists of five steps and two decision points. The steps are explained in greater detail below.

- The first step is to **identify (and document) the need to modify the current process**. Since most service industries are often faced with the difficult task of meeting their mandates with constrained resources, chances are that management
would not fund this effort unless there was a present need (e.g. congressional mandate, new initiative, GAO recommendation). If the current process is working well, this framework may be initiated to observe and analyze how changes to the system (e.g. adding a new workload initiative) would affect the process equilibrium. If the process has known inefficiencies, the framework may be initiated to gain a better understanding of the system and analyze possible solutions. Finally, the framework could be initiated to investigate an inefficient process that will also have to incorporate new initiatives. This framework step also aids the analysis effort because it will establish the need for the analysis project, assist with creating the requirements for the desired state of the organizational process, and unify the goals of the stakeholder group.

- The second step is to **identify the key stakeholders** for the analysis. These individuals must holistically have a working knowledge of the organizational process being analyzed, including (but not limited to) the process steps and the inefficiencies documented in the previous process.

- The third step in the first phase is to **develop a system-level process model and requirement criteria for the desired state of the process**. In this step, the stakeholders previously identified will sit with the analysts to document the current state of the process. This document will serve as the template to create the system dynamics model and the discrete event simulation model in Phase II. This document also helps to conform the mental models of the stakeholders, ensuring that the process is consistently visualized by all parties involved in the analysis process. Requirements for the desired state are also documented within this step.
• The next step in this phase is to **retrieve the relevant data** needed to create a macroscopic (system-level) view of the process documented in the previous step. This data should be readily available and ready for analysis.

• The following step is a decision point in the framework which is used to **assess the sufficiency of the collected data**. If there is not enough data to support the defined process model, the project does not have an analytic solution and the framework cannot be utilized.

• If there is sufficient data, the current state of the process is used to **create a system dynamics model**. The model needs to holistically capture the process and the documented inefficiencies should be observed in the simulation.

• The second decision point in the framework assesses the **completeness of the macroscopic model**. If the model fails to show the process inefficiencies, it is likely missing necessary system components. If this is the case, the process model development and requirement step must be revisited to determine the missing system components and/or data needed to complete the macroscopic model. If the model successfully shows the process inefficiencies, it is likely capturing the system in its entirety. When this occurs, the analyst(s) should proceed to Phase II of the framework.

The Phase I process steps are depicted in the figure on the following page.
Figure 4-2: Framework Phase I: System-Level Process Model Creation
4.2 Framework Phase II: Microscopic Process Evaluation

Phase II consists of six processes and one decision step. The steps are explained in greater detail below.

- The first step is to **identify the rules and assumptions for the simulation model**. In this step, each process segment in the macroscopic process model should be dissected into procedural steps that the simulation will use to imitate the behavior of the organization. The system performance metrics are also explicitly defined, documented, and coded. Any assumptions used to create the simulation data should also be documented and explained.

- The second step is to **create the simulation data**, if necessary. The following resources should be used as guides to make sound judgments:
  - the context of the readily available data,
  - statistical inferences on the readily available data,
  - organizational knowledge,
  - rules and assumption created in the previous step.

- The following step is to **create the simulation model**. This should be a discrete event simulation model that imitates the workload queue(s) within the organization.

- The fourth step is to **run the model**. This initial run is completed to ensure that the system is operating as expected.

- The next step is another decision point within the framework that is used to **assess the consistency of the simulation and the system-level model**. If the simulation is not consistent with the model documentation and macroscopic
model, the simulation rules and assumptions must be revisited.

- If the simulation is consistent with the model documentation and macroscopic model, the **simulation is run 30 times** to create performance data that will be used to statistically assess the system.

- Once the runs are complete, the performance data exports should be summarized to assess the system. Examples of the summary statistics include:
  - Measurement of interest average
  - Measurement of interest median
  - Measurement of interest frequency
  - Measurement of interest utilization

The completion of the summary statistics marks the end of Phase II. The Phase II process steps are depicted in the figure on the following page. The analyst(s) should proceed to Phase III of the framework.
Figure 4-3: Framework Phase II: Microscopic Process Evaluation
4.3 Framework Phase III: Solution Engineering

The last phase of the framework consists of three process steps. The steps are explained in greater detail below.

- The first step is to determine the absorptive capacity of the organization. This will help to evaluate the probability of success of the proposed solutions. If an organization does not have the capacity to implement a proposed solution, the solution becomes infeasible and should not be considered.

- The second step is to use the findings of the microscopic analysis to generate solutions. Considering the absorptive capacity and the bottlenecks within the system, solutions could be produced to mitigate or eliminate the inefficiencies.

- The following step is to assess the implementation risk of each solution. Each solution should be analyzed independently. The solution with the greatest probability of succeeding should be selected.

The selection of the best solution marks the end of Phase III and the end of the framework. The Phase III process steps are depicted in the figure on the following page.
Figure 4-4: Framework Phase III: Solution Engineering
4.4 Framework Assumptions and Limitations in Scope

Though many of the model assumptions used in the framework will be specific to the organization creating the process optimization model, there are a few assumptions that should be considered when adopting this methodology. They are listed below.

- The organization will be satisfied with an acceptable, but reasonably inaccurate, analysis of their process. The lack of data decreases the accuracy of the model findings, but with sound statistical assumptions, the models should be accurate enough to assess major process inefficiencies and feasible solutions.

- The organizational process can be modeled as a queuing model.

- It is appropriate to adopt generally accepted mathematical modeling assumptions when there is not enough data to determine the behavior of an organizational input (e.g. assuming that queue arrivals follow a Poisson distribution and the service times follow an exponential distribution).

- The level of granularity required for data collection and process modeling is at the discretion of the analyst.

Additionally, the framework has a very specific scope. The methodology and analysis techniques presented are only proposed to be used by service industries with limited data that have a need for process optimization. These organizations are assumed to have enough readily available data to implement the analysis framework and have adequate resources to implement at least one feasible solution. Additionally, these agencies are assumed to require a quick analysis turnaround and do not have the time and/or resources to invest in data investigation and cleanup.
Chapter 5. Results

This section demonstrates the framework presented in this praxis by applying it to real-world data. The data used in this illustration were retrieved from various reports from or about the medical product review centers within the Food and Drug Administration (FDA). All of the data used was publicly available and produced by government agencies. It should be noted that the FDA was not formally contacted via Freedom of Information Act Request or any other vehicle for additional information. The insights and conclusions drawn from this section are solely stated to illustrate the applicability of the framework and not to imply any inefficiency within the medical product review centers within FDA or the agency as a whole.

5.1 Phase I: System-Level Process Model Creation

Based on the 16 May 2016 published findings of the Government Accountability Office (GAO), the FDA needs to “engage in a strategic planning process to identify challenges that cut across the medical product centers, and document how it will achieve measurable goals and objectives in these areas” (US Government Accountability Office 2016a). In order to complete this task, the FDA must understand its current operational processes, assess how the processes are currently functioning, and determine challenge areas that should be addressed in the strategic plan.

The key process stakeholders needed to execute the framework are the medical product centers, since they are the entities tasked with completing the strategic plan. It should be noted that the stakeholders are not identified at a granular level because this exercise is only for illustrative purposes and the insights provided by the proposed
framework will not be used. If this illustration was executed internally by the FDA to aid in the creation of a strategic plan, the chosen stakeholders must be people that possess a holistic working knowledge of the organizational process being analyzed, including (but not limited to) the process steps and the inefficiencies. Additionally, according to Jennifer S. Muller (a Wharton management professor), the stakeholder group should be limited to no more than five members in order to avoid diminishing motivation and management issues within the group (Wharton School of the University of Pennsylvania 2006).

The system-level process model map to be used in the framework is illustrated in the figure below. The requirement for the desired state is that the system-level process is stable (i.e. the general flow of the system is at equilibrium) and free of inefficiencies (i.e. bottlenecks).
The following table lists the data elements and data sources that will be used to create the system-level and microscopic process models.
The provided data will be enough to effectively create the system-level system dynamics model as long as the following requirements, caveats, and assumptions were assumed to be true.

- The data provided in the documents are accurate.
- The distributions of the action items are independent and identically distributed.
- Action items receipts are defined as action items that will be reviewed by the respective Centers. Each action item can only be reviewed by one Center and all action items will be reviewed once received.
- The distribution determined by the provided data is assumed to be an adequate measure of the population distribution for each action item type.
- The action item arrivals are assumed to follow stationary Poisson distribution.
- The Center service times are assumed to follow an exponential distribution.
- The action item requests are assumed to be reviewed on a first-come-first-serve basis.
• Each action item type will have a single process and single phase service mechanism.

• The actual Fiscal Year 2013 staffing data is the same as the enacted data, since actual data was not reported.

• The latest performance data for a given fiscal year represents the actual performance data for the respective fiscal year.

• In the case of GDUFA, the time to first cycle approval can be used as the time to first cycle action.

• All action item receipts with an undesignated category will be assigned to the category with the lowest review goal.

• The review goal times, along with the on-time percentages, can be used to adequately predict the review distributions of the action item receipts. Action items that do not have service performance metrics will not be included in the system (since they do not have enough data to model them).

• Staffing levels that are not assigned to a center are not used in the model, since the action item reviews occur within the Centers.

• Budget authority staffing data is not reported using the same categorizations as the action item and user fee staffing data, so it was excluded from the model inputs.

• Combination product data is not available at a level in which it could be tied to the work products in the analysis, so it was excluded.

• Staffing levels for each Center reviewer type is not available, so it is assumed that
an action item review may start as long as there are enough members in the staffing pool to form a review division.

- A reviewer can only be assigned to one action item at a given time.
- Action items that are not part of the current workload process are not included.
- The number of all action item receipts will be zero when the model is initiated (with the exception of the GDUFA backlog data). Additionally, the GDUFA backlog data is reported as a standalone workflow since metrics for the backlog are reported separately in the GDUFA Performance Reports.
- The average transfer rate between centers is consistent over time.
- Each action item requires six Center full-time employees (FTEs). One Field FTE will be assigned to all for original NDA, BLA, efficacy supplement, and prior approval manufacturing supplement reviews.
- Sub-system FTE transfers only consist of Center FTEs.

The analysis tool selected to simulate the system-level system dynamics model of the process map is Stella Architect by isee systems. This proprietary tool has the ability to create system dynamics models, simulate them, and create interfaces on top of the models.

The following figures represent the segments of the system-level system dynamics model for the process map of the medical product centers. The entire model is too large to adequately display. The model segments represent the PDUFA, MDUFA, GDUFA, and BsUFA user fee review systems. The four rectangles at the top of the model are the stocks that represent the user fee FTEs at the Center and Field locations. The other rectangles represent the accumulation of action items in queue for each action item.
category. The two large circles represent the number of review teams needed to meet the demand of the action item receipts and the number of review teams released due to a review being completed. Each sub-system has an interrelationship flow that provides the net inflow of FTEs from other user fee sub-systems. Since it is assumed that each action item can only be reviewed by one Center, FTEs are the only sub-system components that can transfer to and from other sub-systems. It should also be noted that some action items have a delay associated with them. Since all of the action item categories were not implemented within the same timeframe, delays were needed in order to simulate all of the subsystem components in a realistic manner.

The first set of figures presented below show the distribution of the PDUFA Center FTEs, PDUFA Field FTEs, and action items over a span of ten years and 100 years. The distributions show that there is an accumulation of receipts for all of the captured action items (with the exception of the Standard NMEs and BLA action items) and the FTE levels (for PDUFA Center and Field FTEs) are depleted as time progresses. A video showing the simulation for the ten year data may be accessed by clicking here. Figure 5-2 is an image of the ten year results. Figure 5-3 is an image of the 100 year results, which illustrate that the distributions observed in the ten-year run are indicative of the overall state of the system.

---

1 The hyperlink is: https://sims.iseesystems.com/sallamar-worrell/d.eng-video-files/#page1
Figure 5-2: PDUFA Simulation Results for Ten Year Run
Figure 5-3: PDUFA Simulation Results for 100 Year Run
The next set of figures show the distribution of the MDUFA Center FTEs, MDUFA Field FTEs, and action items over a span of ten years and 100 years. Once more, the distributions show that there is an overall accumulation of receipts for all of the captured action items and the FTEs are exhausted as time progresses. During the last MDUFA reauthorization, the majority of action item classifications were changed. Since the model only includes action item categories that are a part of the current MDUFA workload process, the FTE distributions seem sporadic. A video showing the simulation for the ten year data may be accessed by clicking here\(^2\). Figure 5-4 is an image of the ten year results. Figure 5-5 is an image of the 100 year results, which illustrate that the distributions observed in the ten-year run are indicative of the overall state of the system.

\(^2\) The hyperlink is: https://sims.iseesystems.com/sallamar-worrell/d.eng-video-files/#page2
Figure 5-4: MDUFA Simulation Results for Ten Year Run
Figure 5-5: MDUFA Simulation Results for 100 Year Run
The subsequent set of figures show the distribution of the GDUFA Center FTEs, GDUFA Field FTEs, and action items over a span of ten years and 100 years. GDUFA is a new user fee program, but the review processes it supports are not. Due to the immaturity of the user fee program and lack of active congressional reporting mandates, there are only four action item types modeled in this sub-system. Two of the action item types are backlog action items in which the stock values are not equal to zero. The distributions of these action items are decreasing and eventually reach zero. The other two action items show an accumulation of receipts. The FTE levels are depleted over time. GDUFA did negotiate a hiring initiative in their user fee program, which was completed in fiscal year 2015 (U.S. Food and Drug Administration 2016i). For this reason, a constrained growth model was used to simulate the change in the Center FTEs over time. Additionally, GDUFA inspections are expected to decrease by 40% (Nicholls 2015), so a goal seeking model was employed to simulate the Field FTE growth. A video showing the simulation for the ten year data may be accessed by clicking here\(^3\). Figure 5-6 is an image of the ten year results. Figure 5-7 is an image of the 100 year results, which illustrate that the distributions observed in the ten-year run are indicative of the overall state of the system.

---

\(^3\) The hyperlink is: https://sims.iseesystems.com/sallamar-worrell/d.eng-video-files/#page3
Figure 5-6: GDUFA Simulation Results for Ten Year Run
Figure 5-7: GDUFA Simulation Results for 100 Year Run
The last set of figures show the distribution of the BsUFA Center FTEs, BsUFA Field FTEs, and action items over a span of ten years and 100 years. BsUFA is a new regulatory pathway and a new user fee program. The program has very limited data which makes the simulation unrealistic; for example, the Center FTE flow has a decay rate of 61 percent, the Field FTE flow has a decay rate of 100 percent. Additionally, the transfer flow rate of the sub-system is 0.49 FTEs a year. Due to the unrealistic nature of this simulation, it will be removed from the model in Phase II of the framework. A video showing the simulation for the ten year data may be accessed by clicking here\(^4\). Figure 5-6 is an image of the ten year results. Figure 5-7 is an image of the 100 year results, which illustrate that the distributions observed in the ten-year run are indicative of the overall state of the system.

\(^4\) The hyperlink is: https://sims.iseesystems.com/sallamar-worrell/d.eng-video-files/#page4
Figure 5-8: BsUFA Simulation Results for Ten Year Run
Figure 5-9: BsUFA Simulation Results for 100 Year Run
5.2 Phase II: Microscopic Process Evaluation

The distributions presented by the simulation in Phase I of the framework provide evidence that there are bottlenecks in the medical product review process and that the system was not at equilibrium. It also showed that BsUFA would not be appropriate to simulate due to its immaturity. Though the action item category distributions within the GDUFA sub-system appeared to be stable enough to model and the FTE distributions could be projected, many of the action item categories that compose the GDUFA workload process did not have any data associated with them. Since the GDUFA subsystem model is incomplete and will change drastically in the upcoming years, it would also be unsuitable to simulate it in Phase II due to its immaturity.

Phase II aims to take a microscopic look at the medical product review process to further examine the process inefficiencies presented in Phase I. The analysis tool selected to simulate the microscopic discrete event simulation model for the process map is SimEvents by MathWorks. This proprietary tool has the ability to create discrete event simulations and is tightly integrated with MATLAB, thus making it easy to optimize performance metrics with tools such as the genetic algorithm, if needed.

To create the needed parameter inputs for the discrete event simulation, the arrival and service rates for every action category needed to be converted from yearly rates (number of action items received and acted on in a year, respectively) to daily times (number of days between arrivals and actions, respectively). Then, these measures were used to determine the number of user fee FTEs required to stabilize the system. This was accomplished by simulating a daily snapshot of the holistic system process during a user fee reauthorization cycle (five years). The summative findings of the 30 simulation runs...
are provided in the table below. The data parameters provided are:

- Traffic Intensity- how busy the queue is at a given time
- Number of Review Teams Needed to Meet Demand- the number of review teams needed to eliminate the waiting times of the action items
- Mean Number of Review Teams Utilized Over User Fee Reauthorization Cycle- the mean number of review teams utilized by each queue during the simulation
- Median Number of Review Teams Utilized Over User Fee Reauthorization Cycle- the median number of review teams utilized by each queue during the simulation
- Median Utilization of Maximum Review Team Demand- the median percentage of time a review team is being utilized during the simulation

The assumptions provided in Phase I are still applicable and no other assumptions have been applied.
### Table 5-2: Microscopic Process Evaluation Results for PDUFA

<table>
<thead>
<tr>
<th>PDUFA Action Item</th>
<th>Traffic Intensity</th>
<th>Number of Review Teams Needed to Meet Demand</th>
<th>Mean Number of Review Teams Utilized Over User Fee Reauthorization Cycle</th>
<th>Median Number of Review Teams Utilized Over User Fee Reauthorization Cycle</th>
<th>Median Utilization of Maximum Review Team Demand</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Original Priority NMEs and BLAs</strong></td>
<td>15.61</td>
<td>19.00</td>
<td>12.52</td>
<td>13.00</td>
<td>53.86%</td>
</tr>
<tr>
<td><strong>Original Standard NMEs and BLAs</strong></td>
<td>27.93</td>
<td>30.00</td>
<td>21.73</td>
<td>24.00</td>
<td>54.50%</td>
</tr>
<tr>
<td><strong>Original Priority NDAs and BLAs</strong></td>
<td>10.29</td>
<td>13.00</td>
<td>8.20</td>
<td>8.00</td>
<td>58.80%</td>
</tr>
<tr>
<td><strong>Original Standard NDAs and BLAs</strong></td>
<td>76.43</td>
<td>86.00</td>
<td>65.27</td>
<td>71.00</td>
<td>64.21%</td>
</tr>
<tr>
<td>PDUFA Action Item</td>
<td>Traffic Intensity</td>
<td>Number of Review Teams Needed to Meet Demand</td>
<td>Mean Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Utilization of Maximum Review Team Demand</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-------------------</td>
<td>---------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>Class 1 Resubmitted NDAs and BLAs</td>
<td>1.90</td>
<td>4.00</td>
<td>1.64</td>
<td>2.00</td>
<td>34.41%</td>
</tr>
<tr>
<td>Class 2 Resubmitted NDAs and BLAs</td>
<td>21.07</td>
<td>30.00</td>
<td>19.58</td>
<td>20.00</td>
<td>54.09%</td>
</tr>
<tr>
<td>Priority NDA and BLA Efficacy Supplements</td>
<td>16.50</td>
<td>23.00</td>
<td>14.77</td>
<td>15.00</td>
<td>54.37%</td>
</tr>
<tr>
<td>Standard NDA and BLA Efficacy Supplements</td>
<td>103.33</td>
<td>112.00</td>
<td>87.81</td>
<td>96.00</td>
<td>66.46%</td>
</tr>
<tr>
<td>PDUFA Action Item</td>
<td>Traffic Intensity</td>
<td>Number of Review Teams Needed to Meet Demand</td>
<td>Mean Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Utilization of Maximum Review Team Demand</td>
</tr>
<tr>
<td>------------------</td>
<td>-------------------</td>
<td>---------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Class 1 Resubmitted NDA and BLA Efficacy Supplements</td>
<td>1.50</td>
<td>4.00</td>
<td>1.43</td>
<td>1.00</td>
<td>26.81%</td>
</tr>
<tr>
<td>Class 2 Resubmitted NDA and BLA Efficacy Supplements</td>
<td>9.93</td>
<td>13.00</td>
<td>7.72</td>
<td>8.00</td>
<td>54.75%</td>
</tr>
<tr>
<td>NDA and BLA Manufacturing Supplements requiring Prior Approval</td>
<td>294.19</td>
<td>354.00</td>
<td>274.60</td>
<td>281.00</td>
<td>71.61%</td>
</tr>
<tr>
<td>PDUFA Action Item</td>
<td>Traffic Intensity</td>
<td>Number of Review Teams Needed to Meet Demand</td>
<td>Mean Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Utilization of Maximum Review Team Demand</td>
</tr>
<tr>
<td>--------------------------------------------------------</td>
<td>-------------------</td>
<td>---------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>NDA and BLA Manufacturing Supplements Not Requiring Prior Approval</td>
<td>788.43</td>
<td>857.00</td>
<td>715.30</td>
<td>720.00</td>
<td>71.65%</td>
</tr>
<tr>
<td><strong>Type A Meeting Requests</strong></td>
<td>7.64</td>
<td>16.00</td>
<td>7.82</td>
<td>8.00</td>
<td>45.20%</td>
</tr>
<tr>
<td><strong>Type B Meeting Requests</strong></td>
<td>5.91</td>
<td>13.00</td>
<td>5.91</td>
<td>6.00</td>
<td>43.78%</td>
</tr>
<tr>
<td><strong>Type C Meeting Requests</strong></td>
<td>10.37</td>
<td>20.00</td>
<td>10.58</td>
<td>11.00</td>
<td>49.25%</td>
</tr>
<tr>
<td><strong>Type A Meetings Scheduled</strong></td>
<td>64.08</td>
<td>90.00</td>
<td>62.70</td>
<td>63.00</td>
<td>69.14%</td>
</tr>
<tr>
<td><strong>Type B Meetings Scheduled</strong></td>
<td>19.05</td>
<td>28.00</td>
<td>18.26</td>
<td>19.00</td>
<td>62.67%</td>
</tr>
<tr>
<td><strong>Type C Meetings Scheduled</strong></td>
<td>48.83</td>
<td>69.00</td>
<td>47.36</td>
<td>48.00</td>
<td>66.35%</td>
</tr>
<tr>
<td>PDUFA Action Item</td>
<td>Traffic Intensity</td>
<td>Number of Review Teams Needed to Meet Demand</td>
<td>Mean Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Utilization of Maximum Review Team Demand</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-------------------</td>
<td>---------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Type B Written Response</td>
<td>109.03</td>
<td>156.00</td>
<td>103.80</td>
<td>103.00</td>
<td>64.73%</td>
</tr>
<tr>
<td>Type C Written Response</td>
<td>81.29</td>
<td>113.00</td>
<td>76.99</td>
<td>77.00</td>
<td>65.74%</td>
</tr>
<tr>
<td>Meeting Minutes</td>
<td>6.96</td>
<td>12.00</td>
<td>6.90</td>
<td>7.00</td>
<td>55.36%</td>
</tr>
<tr>
<td>Responses to Clinical Holds</td>
<td>58.78</td>
<td>86.00</td>
<td>57.48</td>
<td>58.00</td>
<td>65.97%</td>
</tr>
<tr>
<td>Major Dispute Resolutions</td>
<td>532.66</td>
<td>772.00</td>
<td>545.80</td>
<td>543.00</td>
<td>69.34%</td>
</tr>
<tr>
<td>Special Protocol Assessments</td>
<td>56.26</td>
<td>88.00</td>
<td>53.82</td>
<td>53.00</td>
<td>60.41%</td>
</tr>
<tr>
<td>Review of Proprietary Names Submitted During IND Phase</td>
<td>503.15</td>
<td>547.00</td>
<td>455.00</td>
<td>468.00</td>
<td>74.78%</td>
</tr>
<tr>
<td>PDUFA Action Item</td>
<td>Traffic Intensity</td>
<td>Number of Review Teams Needed to Meet Demand</td>
<td>Mean Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Utilization of Maximum Review Team Demand</td>
</tr>
<tr>
<td>--------------------------------------------------------</td>
<td>-------------------</td>
<td>---------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Review of Proprietary Names Submitted with NDA/BLA</td>
<td>160.88</td>
<td>205.00</td>
<td>150.60</td>
<td>152.00</td>
<td>71.02%</td>
</tr>
<tr>
<td>First-Cycle Filing Review Notifications: NDAs and BLAs</td>
<td>212.82</td>
<td>262.00</td>
<td>206.60</td>
<td>210.00</td>
<td>74.23%</td>
</tr>
<tr>
<td>First-Cycle Filing Review Notifications: Efficacy Supplements</td>
<td>248.29</td>
<td>306.00</td>
<td>238.00</td>
<td>240.00</td>
<td>73.18%</td>
</tr>
<tr>
<td>PDUFA Action Item</td>
<td>Traffic Intensity</td>
<td>Number of Review Teams Needed to Meet Demand</td>
<td>Mean Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Utilization of Maximum Review Team Demand</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-------------------</td>
<td>-----------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Notification of Planned</td>
<td>279.61</td>
<td>335.00</td>
<td>270.30</td>
<td>274.00</td>
<td>74.42%</td>
</tr>
<tr>
<td>Review Timelines: NDAs and BLAs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Notification of Planned</td>
<td>314.28</td>
<td>387.00</td>
<td>305.40</td>
<td>312.00</td>
<td>71.78%</td>
</tr>
<tr>
<td>Review Timelines: Efficacy Supplements</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PDUFA Total</td>
<td>18.40</td>
<td>5050.00</td>
<td>3853.89</td>
<td>3911.00</td>
<td>64.47%</td>
</tr>
</tbody>
</table>
Table 5-3: Microscopic Process Evaluation Results for MDUFA

<table>
<thead>
<tr>
<th>MDUFA Action Item</th>
<th>Traffic Intensity</th>
<th>Number of Review Teams Needed to Meet Demand</th>
<th>Mean Number of Review Teams Utilized Over User Fee Reauthorization Cycle</th>
<th>Median Number of Review Teams Utilized Over User Fee Reauthorization Cycle</th>
<th>Median Utilization of Maximum Review Team Demand</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMA, Panel-Track PMA Supplements, and Premarket Reports-Substantive Interaction</td>
<td>11.46</td>
<td>17.00</td>
<td>10.86</td>
<td>11.00</td>
<td>56.87%</td>
</tr>
<tr>
<td>MDUFA Action Item</td>
<td>Traffic Intensity</td>
<td>Number of Review Teams Needed to Meet Demand</td>
<td>Mean Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Utilization of Maximum Review Team Demand</td>
</tr>
<tr>
<td>-------------------</td>
<td>------------------</td>
<td>-----------------------------------------------</td>
<td>-------------------------------------------------------------</td>
<td>-----------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>PMA, Panel-Track PMA Supplements, and Premarket Reports- Decision with no Advisory Committee input</td>
<td>24.15</td>
<td>30.00</td>
<td>20.72</td>
<td>22.00</td>
<td>55.90%</td>
</tr>
<tr>
<td>PMA, Panel-Track PMA Supplements, and Premarket Reports- Decision with Advisory Committee input</td>
<td>14.11</td>
<td>16.00</td>
<td>9.64</td>
<td>10.00</td>
<td>41.35%</td>
</tr>
<tr>
<td>MDUFA Action Item</td>
<td>Traffic Intensity</td>
<td>Number of Review Teams Needed to Meet Demand</td>
<td>Mean Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Utilization of Maximum Review Team Demand</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>------------------</td>
<td>---------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>180-Day PMA Supplements-</td>
<td>44.35</td>
<td>62.00</td>
<td>43.02</td>
<td>44.00</td>
<td>64.09%</td>
</tr>
<tr>
<td>Substantive Interaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>180-Day PMA Supplements-</td>
<td>121.78</td>
<td>134.00</td>
<td>106.30</td>
<td>115.00</td>
<td>68.48%</td>
</tr>
<tr>
<td>Decision</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Real-Time PMA Supplements-</td>
<td>109.36</td>
<td>123.00</td>
<td>99.54</td>
<td>103.00</td>
<td>75.98%</td>
</tr>
<tr>
<td>Decision</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>510(k) Premarket Notifications-</td>
<td>600.82</td>
<td>787.00</td>
<td>595.40</td>
<td>595.00</td>
<td>72.16%</td>
</tr>
<tr>
<td>Substantive Interaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>510(k) Premarket Notifications-</td>
<td>10162.95</td>
<td>8175.00</td>
<td>5485.00</td>
<td>6059.00</td>
<td>42.76%</td>
</tr>
<tr>
<td>Decision</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDUFA Action Item</td>
<td>Traffic Intensity</td>
<td>Number of Review Teams Needed to Meet Demand</td>
<td>Mean Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Utilization of Maximum Review Team Demand</td>
</tr>
<tr>
<td>-------------------</td>
<td>------------------</td>
<td>---------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>CLIA Waiver by Applications- Substantive Interaction</td>
<td>2.09</td>
<td>4.00</td>
<td>1.88</td>
<td>2.00</td>
<td>36.74%</td>
</tr>
<tr>
<td>CLIA Waiver by Applications- Decision with no Advisory Committee input</td>
<td>5.86</td>
<td>9.00</td>
<td>4.30</td>
<td>4.00</td>
<td>38.44%</td>
</tr>
<tr>
<td>Dual 510(k) and CLIA Waiver by Applications- Substantive Interaction</td>
<td>0.12</td>
<td>1.00</td>
<td>0.50</td>
<td>0.50</td>
<td>8.80%</td>
</tr>
<tr>
<td>MDUFA Action Item</td>
<td>Traffic Intensity</td>
<td>Number of Review Teams Needed to Meet Demand</td>
<td>Mean Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Utilization of Maximum Review Team Demand</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------------</td>
<td>-------------------</td>
<td>----------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>Dual 510(k) and CLIA Waiver by Applications- Decision with no Advisory Committee input</td>
<td>0.40</td>
<td>1.00</td>
<td>0.60</td>
<td>1.00</td>
<td>12.63%</td>
</tr>
<tr>
<td>Standard Original BLAs</td>
<td>6.79</td>
<td>9.00</td>
<td>4.47</td>
<td>5.00</td>
<td>42.05%</td>
</tr>
<tr>
<td>BLA Manufacturing Supplements Requiring Prior Approval</td>
<td>23.62</td>
<td>33.00</td>
<td>21.96</td>
<td>22.00</td>
<td>63.48%</td>
</tr>
<tr>
<td>Standard BLA Efficacy Supplements</td>
<td>2.38</td>
<td>4.00</td>
<td>1.77</td>
<td>2.00</td>
<td>40.78%</td>
</tr>
<tr>
<td>MDUFA Action Item</td>
<td>Traffic Intensity</td>
<td>Number of Review Teams Needed to Meet Demand</td>
<td>Mean Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Number of Review Teams Utilized Over User Fee Reauthorization Cycle</td>
<td>Median Utilization of Maximum Review Team Demand</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>------------------</td>
<td>---------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Class 1 Original BLA and BLA Efficacy Supplement Resubmissions</td>
<td>3.62</td>
<td>8.00</td>
<td>3.34</td>
<td>3.00</td>
<td>38.78%</td>
</tr>
<tr>
<td>Class 2 Original BLA and BLA Efficacy Supplement Resubmissions</td>
<td>0.71</td>
<td>2.00</td>
<td>0.79</td>
<td>1.00</td>
<td>24.62%</td>
</tr>
<tr>
<td>MDUFA Total</td>
<td>2.02</td>
<td>9415.00</td>
<td>6410.08</td>
<td>6999.50</td>
<td>42.05%</td>
</tr>
</tbody>
</table>
5.3 Phase III: Solution Engineering

The purpose of this framework phase is to analyze the data provided in Phases I and II and generate feasible solutions for optimizing the FDA’s organizational process. To complete this phase, the analyst and stakeholders are required to assess the absorptive capacity of the organization, analyze all possible solutions to the process performance issue(s), determine the implementation risk of the possible solutions, and determine the most cost effective, low in risk, and realistic feasible solution(s) to the process inefficiencies.

Absorptive capacity is defined as an organization’s “ability to recognize the value of new information, assimilate it, and apply it to commercial ends” (Cohen 1990). As shown in Phase I, the Center and Field FTEs in every user fee sub-system, were overworked. This is also illustrated in Phase II; the traffic intensities for PDUFA and MDUFA are above one, which shows that the sub-systems are overloaded (i.e. requests are being received faster than they are processed). Therefore, it is highly unlikely that the FDA can successfully re-engineer their internal review process procedures without causing a major disruption to their efficiency. Furthermore, data is not publicly available to model their review processes on a granular level. Since the FDA must review all receipts it receives, the FDA cannot use the insights from this analysis to reduce the action item receipts. Therefore, the only modifiable aspects of the model are the number of action items in queue and the number of FTEs.

Since the only modifiable aspects of the model are the number of action items in queue and the number of FTEs, the list of possible solutions becomes:

- Hire new employees
• Create an approach that hires new employees and increases the average number of action items in queue
• Allow staff to review multiple action item categories when available (e.g. maximize utilization of FTEs)

The results from the analysis in Phase II provided the number of review teams needed in order to meet the demand for action item reviews (e.g. the number of review teams needed to not have a queue of waiting action items). Using the assumption about review team composition, the required number of review teams can be converted into the number of needed FTEs. The FTE summary is shown below. As stated in the Phase I model assumptions, it is assumed that a reviewer can only be assigned to one action item at a given time.

Table 5-4: Required Number of FTEs to Sustain PDUFA and MDUFA Demand

<table>
<thead>
<tr>
<th>User Fee</th>
<th>Number of Review Teams Required</th>
<th>Number of Center FTEs Required</th>
<th>Number of Field FTEs Required</th>
<th>Total Number of FTEs Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDUFA</td>
<td>5,050</td>
<td>30,300</td>
<td>637</td>
<td>30,937</td>
</tr>
<tr>
<td>MDUFA</td>
<td>9,415</td>
<td>56,490</td>
<td>46</td>
<td>56,536</td>
</tr>
<tr>
<td>Total</td>
<td>14,465</td>
<td>86,790</td>
<td>683</td>
<td>87,473</td>
</tr>
</tbody>
</table>

The Phase II results also show that the maximum utilization of a review team in this
scenario is 76%. This means, that at best, an employee will have 24% down time, on average. Furthermore, the FY2015 staffing levels for the user fees are 2,733 PDUFA Center FTEs, 52 PDUFA Field FTEs, 459 MDUFA Center FTEs, and 10 MDUFA Field FTEs (U.S. Food and Drug Administration 2016c). To implement this solution, the FDA would need to hire 27,567 PDUFA Center FTEs, 585 PDUFA Field FTEs, 9,3691 MDUFA Center FTEs, and 36 MDUFA Field FTEs within five years. Since the FDA already has issues hiring talent (Wechsler 2016), the risk of this solution not being realized is very high; this solution should be avoided.

Since the service times are assumed to be equivalent to the action item goal duration, creating a model that allows additional review time for an action item may cause the FDA to not meet its commitments to industry. Implementing this solution has a high probability of negatively affecting the efficiency of the FDA and is not advised.

The last solution involves increasing the utilization of the user fee systems. Since every action item category has a different arrival and service time, it was not possible to model the different action item categories as one queue. However, the summary findings could be aggregated to determine the number of FTEs needed to ensure a certain utility, on average. Using the findings from Phase II, the OPM website, and FDA reports, the following information can be deduced.
These findings suggest a staffing deficit of 2,721 PDUFA Center FTEs, 454 PDUFA Field FTEs, 11,055 MDUFA Center FTEs, and 23 MDUFA Field FTEs. Though these shortages are still large, they are better estimates that the first proposed solution and less risky. This option would be the best option.
Chapter 6. Conclusions and Future Research

The framework successfully met the research objective: to produce a framework that enables service industries with limited data to holistically model, understand, and reform (if needed) their organizational processes using the data that is readily available. As illustrated in the case study, the framework also aided in the development of process optimization insights that are cost effective, low in risk, and considerate to the absorptive capacity of the agency.

Additionally, the research questions were effectively answered. A system-level process map that illustrates the known issues of a service agency with limited data can be created and the bottlenecks within the system-level process can be identified quickly using the process map. This was shown in Phase I of the framework illustration with the system dynamics model. The identified system-level process can be simulated to model the daily operations of the service agency and the bottlenecks can be observed and pinpointed on a granular level (e.g. daily basis). This was demonstrated in Phase II of the framework presentation with the discrete event simulation. Finally, the findings from the simulation model can be used to create process optimization insights that are cost effective, low in risk, and considerate to the absorptive capacity of the agency; this was illustrated in Phase III of the framework demonstration.

Moreover, all of the alternative hypotheses were accepted. They are listed below.

H1a: A system-level process map, denoted as q, that illustrates the known issues of a service agency with limited data can be created.

\[ H1_a: \exists q \in \mathbb{N} \]

(6.1)

H2a: The bottlenecks of the system-level process, denoted as u_q, can be
identified using the process map.

\[ H2_a : \quad \sum u_q > 0 \quad (6.2) \]

H3a: The identified system-level process, denoted as \( v \), can be simulated to model the daily operations of the service agency.

\[ H3_a : \quad \exists \ v \in \mathbb{N} \quad (6.3) \]

H4a: The bottlenecks, denoted as \( u_g \), can be observed and pinpointed on a granular level.

\[ H4_a : \quad \sum u_g > 0 \quad (6.4) \]

H5a: The findings from the simulation model, denoted as \( w \), can be used to create process optimization insights, denoted as \( y \), that are cost effective, low in risk, and considerate to the absorptive capacity of the agency.

\[ H5_a : \quad y \in w \quad (6.5) \]

Though the framework was successful, the case study illustration revealed some limitations with the data. Though the framework was created to deal with limited data and shortcomings in the results were expected, the FTE projections were higher than anticipated. This is most likely due to the fact that certain information, which would be readily assessable if the framework was to be used internally, had to be assumed for the purpose of the framework illustration (e.g. the review team size for MDUFA applications and the number (and review duration) of Field employees assigned to each application). Future research in this area could include obtaining more source data from the organization being studied via a FOIA request. In addition, future researchers could inquire about missing data (e.g. the review team size for MDUFA applications and the
number (and review duration) of Field employees assigned to each application) before making a general assumption.
References


Nicholls, Alan W. 2015. GDUFA: UNINTENDED CONSEQUENCES THAT NEED TO BE FIXED. Bulk Pharmaceuticals Task Force.


86


Wharton School of the University of Pennsylvania. 2006. Knowledge @ Wharton. In Is Your Team Too Big? Too Small? What's the Right Number? Philadelphia: Wharton School of the University of Pennsylvania.,
