Application of Risk Management Frameworks to Medical Device Production Development

by

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B.S. Mechanical Engineering, University of Virginia, 2014

Submitted to the Mechanical Engineering Department and the MIT Sloan School of Management in Partial Fulfillment of the Requirements for the Degrees of

Master of Science in Mechanical Engineering
and
Master of Business Administration

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Abstract

Effective risk management is critical when manufacturing medical products to avoid any potential impact to patients due to supply disruptions or quality excursions. As Flex LTD, an end-to-end manufacturing solutions provider, continues to grow its medical device portfolio, they have a need to take a more proactive and systematic approach to managing project risks. This research applies several project risk management frameworks and interventions to one of Flex’s medical device programs as a pilot study. First the current state of existing risk management practices is evaluated. The frameworks and interventions are then implemented over a period of 6 months and their effectiveness analyzed at the end of the study.

The results found that the interventions and frameworks applied during the pilot study improved overall understanding of fundamental risk management concepts. It also showed that key activities, such as training workshops and the intervention of a risk management “champion” impacted risk tracking activities and were effective for overcoming adoption barriers. In applying the Risk Driver framework to the data generated during the pilot study, it was determined that identifying commonalities and trends across risk drivers can be used to proactively inform risk management decision-making and establish new metrics. These results also show that useful insights can be derived from risk drivers without knowing the outcome of the risk event. The study concludes that while risk management has both cultural and structural components, changes to the structural aspects (tools and processes) enable cultural change. Additionally, it concludes that frameworks can be used facilitate proactive risk management if they are integrated into a robust overarching risk management process.

Recommendations for future work include improving training programs to educate team members about project risk management, as well as the development of simple frameworks that are integrated into the overall risk management process to enable more proactive risk management. Certain risk management interventions such as trainings and having an assigned “Champion” for risk management are effective in the near term, but further study is needed to evaluate their impact on long-term sustainability.

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# Table of Contents

Abstract ........................................................................................................................................... 3
Acknowledgements .......................................................................................................................... 5
Table of Contents ............................................................................................................................ 7
List of Figures .................................................................................................................................. 10

1 Introduction ................................................................................................................................... 13
   1.1. Project Context ................................................................................................................... 13
   1.2. Project Motivation ............................................................................................................. 15
   1.3. Problem Definition ............................................................................................................ 16
   1.4. Research Questions ......................................................................................................... 17
   1.5. Research Methods ............................................................................................................. 18
   1.6. Thesis Results & Contributions ...................................................................................... 19
   1.7. Thesis Outline .................................................................................................................. 19

2 Literature Review ....................................................................................................................... 21
   2.1. Introduction ....................................................................................................................... 21
   2.2. Industry Standards for Risk Management ............................................................................ 21
   2.3. Review of Risk Management Frameworks ......................................................................... 23
   2.4. Systemic Risk Approaches ............................................................................................... 27
      2.4.1. Leading Indicators and STAMP................................................................................ 28
      2.4.2. Risk Driver Model ..................................................................................................... 28
   2.5. Principles as a Foundation for Frameworks ....................................................................... 30
   2.6. Chapter Summary .............................................................................................................. 30

3 Current State of Risk Management at Flex .................................................................................. 31
   3.1. Introduction ....................................................................................................................... 31
   3.2. The CGM Program ............................................................................................................ 31
   3.3. Research Approach .......................................................................................................... 32
   3.4. Organizational-Level Assessment .................................................................................... 32
      3.4.1. SHIELD .................................................................................................................. 32
      3.4.2. Medical PM 2.0 ..................................................................................................... 37
      3.4.3. PM Prime ................................................................................................................ 39
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.4.4. Integration of Tools and Initiatives</td>
<td>40</td>
</tr>
<tr>
<td>3.5. CGM Program Assessment</td>
<td>41</td>
</tr>
<tr>
<td>3.6. Chapter Summary</td>
<td>43</td>
</tr>
<tr>
<td>4 Application of Risk Management Frameworks</td>
<td>45</td>
</tr>
<tr>
<td>4.1. Introduction</td>
<td>45</td>
</tr>
<tr>
<td>4.2. Pilot Study Approach</td>
<td>45</td>
</tr>
<tr>
<td>4.2.1. Pilot Study Timeline</td>
<td>46</td>
</tr>
<tr>
<td>4.2.2. Defining Risk Management</td>
<td>47</td>
</tr>
<tr>
<td>4.2.3. Applying Frameworks</td>
<td>48</td>
</tr>
<tr>
<td>4.2.4. “Champion” for Risk Management</td>
<td>54</td>
</tr>
<tr>
<td>4.2.5. Communicating Changes and Educating Team Members</td>
<td>55</td>
</tr>
<tr>
<td>4.3. Risk Driver Analysis Methodology</td>
<td>57</td>
</tr>
<tr>
<td>4.3.1. Risk Driver Model</td>
<td>57</td>
</tr>
<tr>
<td>4.3.2. Risk Driver Identification</td>
<td>58</td>
</tr>
<tr>
<td>4.3.3. Risk Driver Analysis</td>
<td>58</td>
</tr>
<tr>
<td>4.4. Chapter Summary</td>
<td>59</td>
</tr>
<tr>
<td>5 Pilot Study Results</td>
<td>61</td>
</tr>
<tr>
<td>5.1. Evaluation Criteria</td>
<td>61</td>
</tr>
<tr>
<td>5.2. Evaluation Methodology</td>
<td>62</td>
</tr>
<tr>
<td>5.2.1. SHIELD Risk Register Historical Data</td>
<td>62</td>
</tr>
<tr>
<td>5.2.2. Evaluation Surveys</td>
<td>64</td>
</tr>
<tr>
<td>5.3. Effectiveness of Interventions</td>
<td>64</td>
</tr>
<tr>
<td>5.3.1. “Champion” for Project Risk Management</td>
<td>64</td>
</tr>
<tr>
<td>5.3.2. Risk Workshops</td>
<td>66</td>
</tr>
<tr>
<td>5.4. Process &amp; Tool Adoption</td>
<td>68</td>
</tr>
<tr>
<td>5.4.1. Project Risk Management Process</td>
<td>69</td>
</tr>
<tr>
<td>5.4.2. SHIELD Tool</td>
<td>70</td>
</tr>
<tr>
<td>5.5. Sustainability of Improved Practices</td>
<td>73</td>
</tr>
<tr>
<td>5.5.1. Stakeholder Buy-in</td>
<td>73</td>
</tr>
<tr>
<td>5.5.2. Understanding of Fundamental Principles</td>
<td>75</td>
</tr>
<tr>
<td>5.5.3. Long-term Ownership</td>
<td>76</td>
</tr>
</tbody>
</table>
List of Figures

Figure 1. Worldwide Flex locations........................................................................................................... 13
Figure 2. Flex’s organizational structure ................................................................................................... 15
Figure 3. The ISO 31000 risk management process [6].............................................................................. 24
Figure 4. The ISO 14971 standard risk management process [7]............................................................. 25
Figure 5. The benefits of using risk registers to record risks [17]............................................................. 27
Figure 6. The Risk Driver Model ............................................................................................................... 29
Figure 7. Risk priority matrix in SHIELD based on probability and impact .............................................. 35
Figure 8. SHIELD Risk Register entry fields .......................................................................................... 35
Figure 9. Current state of HRS program management roles and responsibilities................................. 38
Figure 10. Proposed GTPM program management roles and responsibilities......................................... 39
Figure 11. The PM Prime training modules for program managers.......................................................... 40
Figure 12. Opportunities to incorporate new risk management tools and initiatives.............................. 41
Figure 13. Examples of non-risk entries in CGM Program risk registers ................................................. 42
Figure 14. Risk entry modifications made between January and June of 2018........................................ 43
Figure 15. The CGM Program project risk management process flow diagram ....................................... 49
Figure 16. Expanded Risk Driver Model ................................................................................................. 51
Figure 17. The Risk Driver Model .......................................................................................................... 51
Figure 18. A simple decision protocol ...................................................................................................... 53
Figure 19. A decision protocol for distinguishing between a risk or an issue ............................................ 53
Figure 20. An expanded decision protocol for distinguishing between a risk or an issue ............................ 54
Figure 21. Workshop 2 Risk Response Planning Activity .......................................................................... 57
Figure 22. The Risk Driver Model .......................................................................................................... 58
Figure 23. The SHIELD historical data traceability function ................................................................. 63
Figure 24. Example of historical data recorded in SHIELD for Risk ID #1967 ......................................... 63
Figure 25. CGM Program risk entry modifications over time .................................................................. 65
Figure 26. Risk management process understanding before and after the first Risk Workshop .............. 66
Figure 27. The CGM Program team’s assessment of the first Risk Workshop .......................................... 67
Figure 28. The CGM Program team’s assessment of Risk Workshop 1 and 2 ........................................... 67
Figure 29. Risk management practice sustainability after the workshops ............................................... 68
Figure 30. The CGM Program team’s assessment of risk management ability ........................................ 69
Figure 31. New CGM Program risks recorded over time .......................................................................... 71
Figure 32. CGM Program risks closed over time ...................................................................................... 72
Figure 33. The CGM Program team’s ability to use SHIELD to track risks .............................................. 73
Figure 34. Engagement with SHIELD Risk Register after interventions .............................................. 74
Figure 35. Effectiveness of SHIELD and the Risk Management process .............................................. 75
Figure 36. The CGM Program team’s assessment of the value of risk management .............................. 75
Figure 37. The CGM Program team’s ability to distinguish between risks and issues ............................... 76
Figure 38. The CGM Program team’s understanding of the risk management process ........................... 76
Figure 39. The frequency of occurrence of risk drivers for the CGM Program ....................................... 80
Figure 40. CGM Program cross-functional and total risks categorized by functional area ...................... 84
Figure 41. Risk linkages between functional areas ................................................................................... 84
Figure 42. Map of new technologies, processes, and people ................................................................... 87
Figure 43. SHIELD tool risk register with “Issue or Risk” column added ............................................. 91
Glossary

These terms may not be explicitly defined in the text but are useful in the context of the research presented.

Definitions

Concern – A matter that causes feelings of unease, uncertainty, or apprehension. In the context of this work, it is used to represent ideas that have not yet been sufficiently defined to be classified as risks, issues, or problems.

Decision Protocol – A decision support tool that model conditional decisions and their possible consequences.

Issue – An event that has already happened and has impacted or is currently impacting project objectives. In the context of this work, this definition is expanded to include events that have not yet occurred but are certain or almost certain to occur.

Outcome Drivers – Conditions of the environment, the system and the people in the system, that affect the magnitude of the outcome of a risk event if it occurs.

Pilot Study – A sustained engagement over a period of time, during which specific interventions are implemented and studied.

Problem – An event or condition that has already occurred, negatively impacts project objectives, and can be mitigated by individuals who understand what actions to take.

Program – A highly complex project or a group of related projects managed in a coordinated way.

Risk – The effect of uncertainty on outcomes. In the context of this work, risk is defined more narrowly as a specific uncertain event that, if it occurs, has a positive or negative effect on a project’s objectives. The severity of the event combined with the probability that the event will occur determines the level of risk.
**Risk Drivers** – General conditions of the system, stakeholders, and environments that contribute to a heightened state of risk.

**Risk Event** – A specific uncertain event that might occur.

**Risk Outcome** – A potential outcome that will result if a risk event does occur.

**SHIELD** – An online program management tool developed internally by Flex’s High Reliability Solutions group. Its purpose is to provide a centralized location for documenting and tracking the progress of a program from beginning to end. It includes features for program management such as volume targets, milestone and action item trackers, and risk registers.

**Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous Glucose Monitor</td>
<td>CGM</td>
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<td>Electronics Manufacturing Services</td>
<td>EMS</td>
</tr>
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<td>Food and Drug Administration</td>
<td>FDA</td>
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<td>Global Account Manager</td>
<td>GAM</td>
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<td>Global Technical Program Manager</td>
<td>GTPM</td>
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<td>High Reliability Solutions</td>
<td>HRS</td>
</tr>
<tr>
<td>International Organization for Standards</td>
<td>ISO</td>
</tr>
<tr>
<td>New Product Introduction</td>
<td>NPI</td>
</tr>
<tr>
<td>Original Equipment Manufacturer</td>
<td>OEM</td>
</tr>
<tr>
<td>Process Failure Mode Effects Analysis</td>
<td>PFMEA</td>
</tr>
<tr>
<td>Program (Project) Manager</td>
<td>PM</td>
</tr>
<tr>
<td>Project Management Body of Knowledge</td>
<td>PMBOK</td>
</tr>
<tr>
<td>Project Risk Management</td>
<td>PRM</td>
</tr>
<tr>
<td>Simplified Handshake to Inform, Execute, Launch, and Deliver</td>
<td>SHIELD</td>
</tr>
<tr>
<td>Surface Mount Technology</td>
<td>SMT</td>
</tr>
<tr>
<td>System-Theoretic Accident Model and Processes</td>
<td>STAMP</td>
</tr>
</tbody>
</table>
1 Introduction

1.1. Project Context

*Historical Background*

Flex LTD is a multinational manufacturing company that provides design, engineering, production, and supply chain services and solutions to original equipment manufacturers. Flex, formerly Flextronics, Inc., was founded in Silicon Valley in 1969 and started out making circuit boards. It became a publicly held company in 1981 and grew from a multi-million to a multi-billion-dollar business during the 1990s. In 2015, Flex officially shed "-tronics" from their name, signaling both a growing focus on business outside the electronics industry and an expansion of services to include product design. Rebranding their new strategy as *Sketch-to-Scale™*, Flex reflected in their 2018 Annual Report that "Over the past several years, we have evolved beyond a traditional Electronics Manufacturing Services ("EMS") company, and now consider Flex to be a provider of a full range of *Sketch-to-Scale™* services." Today, Flex employs roughly 200,000 people at more than 100 sites in 30 different countries and earns over $25 billion in annual revenue. They serve many different industries, doing more than $1 billion worth of business with the Medical Devices, Automotive, Consumer Products, and Energy industries, among others. [1]

![Worldwide Flex locations](image)

*Figure 1. Worldwide Flex locations*
Flex has over 30 years of experience in the medical industry. In the 2000s, Flex focused on developing their medical business as part of their overall growth strategy. In their 2005 Annual Report, Flex stated that “we believe that there are significant growth opportunities for EMS providers to win additional business from OEMs in certain markets or industry segments that have yet to substantially utilize EMS providers, such as the Japanese market and the industrial, medical and automotive industry segments.” In 2003, less than 7% of Flex’s revenues were derived from customers in the industrial, medical, and automotive industries. [2] These industries generated 15% of total revenue by 2007, and as of 2018 generated over 40% of Flex’s total revenue [1].

Organizational Structure
Flex’s organizational structure is highly decentralized, defined by lean corporate management and a network of factories around the world that operate almost entirely independent from one another. Flex’s business with certain strategic industry partners are managed by the High Reliability Solutions (HRS) group and Integrated Solutions group, with HRS focusing on Health Solutions and Automotive. Some of Flex’s factories report up through Flex’s HRS Operations group, while others report up through Flex’s Global Operations group. There are also dotted-line reporting relationships between some factories and HRS Operations or Global Operations. Flex’s high-level organizational structure is outlined in Figure 2.
1.2. Project Motivation

Effective risk management is key in almost any industry. It is particularly critical in the manufacture of medical products. Not only is it essential to avoid any potential impact to patients due to supply disruptions and quality excursions, but also medical device manufacturing processes are highly regulated by the Food and Drug Administration (FDA) and must meet stringent compliance parameters. Failure to adhere to these standards could have major cost and reputation implications for a company. Additionally, risk management can help avoid cost increases due to unanticipated events, scope changes, problems, and delays. Even anticipated issues can add cost if they are not appropriately evaluated and mitigated. Many medical device companies elect to manufacture their own products, and in scenarios where they do outsource, they expect the external entity to demonstrate robust and reliable risk management systems.
Flex has decades of experience working with the medical and health industry, focusing on medical devices, drug delivery solutions, and diagnostic and medical equipment. Flex’s medical business is managed under the High Reliability Solutions (HRS) group, which includes both the Health Solutions and Automotive groups. In recent years, the Health Solutions group has been increasing their medical device business, both in terms of revenue and proportion of Flex’s overall business. Additionally, Flex has been engaged by one of their major customers in the medical device industry to design, construct, and operate what is likely one of the largest medical device manufacturing systems ever outsourced to a contract manufacturer. As HRS continues to take on larger-scale medical projects and expand its portfolio, their leadership has identified a need to take a more proactive and systematic approach to managing risk.

1.3. Problem Definition

The problem this thesis will address was initially presented as a need for Flex’s Health Solutions group to develop a culture of proactive risk management. This problem definition was refined to a need for Flex to develop frameworks to enable proactive risk management. At the outset of the project, it was necessary to define the scope of the project approach and specify the meaning of risk management within the context of the problem.

Project Scope

In January of 2018, Flex began product development on a high-volume medical device program for one of their largest customers in the medical industry. The product, a disposable continuous glucose monitor (CGM), was to be made at one of Flex’s HRS factories in the Chicago area and expected to be launched within the next 18 months. It was decided to implement and evaluate improved risk management practices on this particular program as a pilot study. The key factors that made the program an appropriate choice include the relatively high risk-level of the program, due to its scale, complexity, and aggressive timeline, and the criticality of mitigating risks to help ensure an on-time product launch, so as to meet patient demand. Since the program was in production development at the time of the project, this project focuses on the application of risk management to the production development phase of manufacturing. Learnings from the pilot are used to develop a model that will be scalable across the Health Solutions group and other organizations across Flex.
Problem Statement

Due to the particular risks intrinsic to the medical device industry and Flex’s growing medical business, it is critical for the Health Solutions group to have a robust system of risk management, and particularly project risk management. The problem statement can be defined more clearly in the following parts:

- Flex’s decentralized organizational structure inhibits standardization and knowledge-sharing across factory sites, which has led to (i) a lack of common language and frameworks to define and assess risks and (ii) limited standardized risk management processes and tools common to Flex or the Health Solutions organization.
- Flex’s perceived existing culture of reactive problem-solving without clear prioritization is a barrier to establishing risk management practices and accountability in the Health Solutions group.

In summary, Flex’s ultimate goal is to establish and pilot improved project risk management practices, with a particular focus on the Health Solutions group. In order to accomplish this, it is necessary to overcome the existing cultural and organizational barriers.

1.4. Research Questions

The remainder of this thesis will address the following research questions within the context of the organizational environment at Flex:

Project Risk Management Frameworks

What are the critical elements to establish foundations for an effective project risk management system in a medical device manufacturing environment? How can frameworks be utilized to clarify fundamental principles and inform decision-making in a timely manner for relevant stakeholders? Will clear definitions of risk and risk management improve understanding of the fundamental concepts and importance of managing risk?

Effective Interventions

Can a “champion” for risk management create behavioral change that is effective and sustainable? What kinds of interventions are the most effective and sustainable? How can Flex
use this information to develop a strategy for continuing to implement change in other parts of the organization?

**Risk Management Culture**

Is risk management a function of organizational culture? If so, can changes to risk management tools, processes, and frameworks drive changes in culture? By developing structured ways to address and manage risks, will Flex leadership be able to more effectively communicate risk management priorities across the organization?

### 1.5. Research Methods

The overall methodology of this research follows the Action Research method. This method is described by Westbrook (1995) as a variation of case research, in which the researcher is a participant in the implementation of a system as well as an evaluator of a specific intervention technique [3]. The Action Research method is employed here in order to simultaneously develop a solution and understand its effects in practical deployment. The phases of this methodology are described below:

1. **Current State Analysis** – a current state analysis is performed in order to document the baseline project risk management activities already in use by Flex’s program management teams at the factory site as well as at the corporate level.

2. **Development of Frameworks** – a series of frameworks are developed to facilitate the implementation of improved project risk management practices through the clarification of fundamental risk management concepts and processes.

3. **Pilot Implementation** – the developed interventions are implemented on a particular medical device program in the production development phase. The purpose of the pilot study is to both implement improvements to risk management processes, tools, and methodologies as well as evaluate the effectiveness of the interventions through surveys and data analysis.

4. **Risk Driver Analysis** – risk data derived from the pilot implementation phase is further analyzed using the Risk Driver framework to identify risk driver trends and evaluate how this information can be used to inform decision-making.
5. **Integration** – provide recommendations for integration of frameworks into company-wide processes and tools.

### 1.6. Thesis Results & Contributions

This thesis applies both existing and new ideas in a new environment. Specifically, it applies existing frameworks, such as decision protocols and the Risk Driver Model, in new ways to increase the effectiveness of risk management interventions. It also applies established interventions via a pilot study, such as process flow maps, training, and an individual “Champion” to drive change, and analyzes their effectiveness within the Flex medical device production development environment. The results show a correlation between the interventions implemented during the pilot study by the “Champion” to increased and more regular risk management activity. The results also show that the interventions and applied frameworks improved overall understanding of fundamental risk management concepts. One major conclusion of this thesis is that frameworks can be used facilitate proactive risk management if they are integrated into a robust overarching risk management process. Certain risk management interventions such as trainings and having an assigned “Champion” for risk management are effective in the near term, but further study is needed to evaluate their impact on long-term sustainability.

Additionally, instead of retroactively assessing risk drivers after a risk event has occurred, this thesis seeks to understand whether risk drivers can be proactively assessed in order to inform risk management before a risk event has occurred. A key finding is that certain risk drivers, such as an aggressive project schedule and highly cross-functional team dynamics, can be common to many different risks. This commonality enables insights to be applied broadly both as risk interventions as well as to inform decision-making and the establishment of new metrics. These results also show that useful insights can be derived from risk drivers without knowing the outcome of the risk event.

### 1.7. Thesis Outline
The thesis is organized into seven chapters. Chapter 2 provides an overview of the prior work and literature that the thesis foundation is built on, including academic literature, professional standards, and prior theses. This literature review covers three main topic areas: Industry Standards, Frameworks, and the Risk Driver Model.

Chapter 3 discusses the current state of risk management at Flex, including the evaluation methodology and results. This chapter also includes background information about the CGM Program.

Chapter 4 provides an overview of the approach taken to apply risk management frameworks to a medical device program in the production development phase. This approach encompasses two primary components: the pilot study, which is implemented on the CGM Program, and Risk Driver analysis.

Chapter 5 contains the pilot study evaluation methodology and results. The analysis of the results focuses on the effectiveness of the interventions implemented during the pilot study, the level of process and tool adoption as a result of the pilot study, and the likelihood that the improved practices established during the pilot study will be sustained.

Chapter 6 discusses the Risk Driver analysis performed on the risk data generated during the pilot study. Risk Drivers common across many individual risks are identified, and those with the highest frequency of occurrence are assessed to derive insights that may inform risk management decision-making.

Chapter 7 provides a conclusion as to what can be derived from the results of this research and recommendations for future work based on the findings in this thesis.
2 Literature Review

2.1. Introduction

The development and application of the risk management frameworks for this research builds on existing work related to project risk management standards and tools and their applications. Project risks affect outcomes in many industries, including the medical device industry [4]. Risk management is a means of improving the likelihood of success for highly complex engineering projects [5], such as medical device product development. Yet studies show that the adoption of risk management practices by project managers is varied [6]. The findings of Olechowski et al (2016) reinforce that risk management is a critical element of engineering project management and enables structured decision making [5]. The following chapter reviews the characteristics and limitations of existing standards, processes, and tools that provide frameworks for risk management and decision-making.

2.2. Industry Standards for Risk Management

*ISO 31000*

The ISO 31000:2009 Standard was prepared by the ISO Technical Management Based Working Group on risk management [6]. It introduces a working definition of risk and eleven risk management principles that, if complied with, will lead to effective risk management. Risk is defined as “the effect of uncertainty on objectives.” Since the uncertainty and the objectives are specific to the context, the risk management system should be tailored to a specific application in every case. The guidance provided asserts that risk management provides information to help managers make appropriate decisions between alternative actions. Additionally, the risk management system should also be systematic and structured such that the strategy can be implemented into a standard system providing efficient and consistent results. The eleven risk management principles are:

1. Risk management creates value
2. Risk management is an integral part of organizational processes
3. Risk management is part of decision making
4. Risk management explicitly addresses uncertainty
5. Risk management is systematic, structured and timely
6. Risk management is based on the best available information
7. Risk management is tailored
8. Risk management takes human and cultural factors into account
9. Risk management is transparent and inclusive
10. Risk management is dynamic, iterative and responsive to change
11. Risk management facilitates continual improvement.

ISO 14971
The ISO 14971 Standard is an international standard for risk management specifically devised for the development of medical devices [7]. The standard is intended to help manufacturers to establish a full risk-management process that includes the identification of hazards, the assessment of the related risks, and the implementation of risk control measures. A specific risk management standard for medical devices is required due to the unique risks that can expose the patient, the operator, the caregiver, and the environment to hazards. ISO 14971 introduces a risk management process and is organized in the following parts:
  Part 1—Establishing the scope of the standard;
  Part 2—Defining terms;
  Part 3—Establishing a risk management framework;
  Part 4—Performing the risk analysis;
  Part 5—Evaluating risk for each identified hazardous situation.
  Part 6—Developing risk control measures when risks are unacceptable;
  Part 7—Evaluating the residual risk posed by risk control measures;
  Part 8—Reviewing risk management process and reporting on the review;
  Part 9—Monitoring device during production and postproduction.

PMBOK
The Project Management Body of Knowledge (PMBOK) is a document created by the Project Management Institute to provide a set of standard terminology and guidelines for project management. The PMBOK is widely used by project management practitioners in industry. These guidelines generally consist of a list of so-called “best practices” in risk management, assumed to be captured from experience and lessons learned over time; however, the guidelines
fail to include evidence to support the effectiveness of their prescriptions [5]. A study investigating specific methods extracted from it found that risk-related methods were found to be the least used of 10 knowledge areas. The authors found a significant difference in the level of use of risk management methods between the successful and unsuccessful projects in the study, suggesting that even though infrequently used, the more risk management, the better project outcomes. This trend is attributed to project managers’ tendency to focus more on areas that are better established than risk, such as time, cost, and scope, and to avoid thinking about what could go wrong with a project [8].

2.3. Review of Risk Management Frameworks

This section provides a general overview of two of the most commonly used frameworks for project risk management in industry: the risk management process and the Risk Register. There are many other standards, tools, and processes used for risk management. Raz and Michael (2001) identify 28 tools that are used by organizations in support of project management performance [9]. Examples of such tools include simulation, brainstorming, and checklists. These tools are not mutually exclusive, and it is not uncommon for a combination of frameworks to be employed [7].

Risk Management Processes

There are several versions of the project risk management process. According to Boehm (1991), there are two phases: 1) risk assessment, which includes “identification, analysis and prioritization; and 2) risk control, which includes risk management planning, risk resolution and risk monitoring planning, tracking and corrective action” [10]. Fairley (1994) specifies seven steps as “(1) Identify risk factors; (2) Assess risk probabilities and effects; (3) Develop strategies to mitigate identified risks; (4) Monitor risk factors; (5) Invoke a contingency plan; (6) Manage the crisis; (7) Recover from the crisis” [11]. The ISO 31000 Standard defines the risk management process (Figure 3), which includes the following components:

- Communication and consultation takes place throughout the process and involves information sharing with the various internal and external stakeholders.
• Establishing the context requires the organization to set the objectives and boundaries of the risk management system with a reasonably implementable scope.

• The risk assessment process is comprised of three steps, identification, analysis, and evaluation. In this process, all of the various risks should be identified, their magnitudes estimated and compared, and ultimately prioritized for action.

• Risk treatment involves the selection of certain mitigation actions which are designed to reduce the likelihood or consequences of specific risks and are implemented according to their residual risk priority. Risk treatment also includes the acceptance of risks which have low likelihood and/or consequences.

• Monitoring and review can be periodic or triggered by certain events but should involve an assessment of the risk management system, identification of emerging risks, re-evaluation of the current assessments, and monitoring of the outputs of the system.

Lastly, the risk management system should be recordable to provide a mechanism for the decisions made to be traced to the risk evaluation outputs and justified based on rationale. [12]

Figure 3. The ISO 31000 risk management process [6]
The FDA-approved ISO 14971 standard specifies a risk management process (Figure 4) specifically tailored to medical device manufacturers. This process is applied to manage risks associated with the product rather than the overall project, which is an important distinction from the more general risk management process defined in ISO 31000. Another key differentiation between the ISO 31000 risk management process is that the main elements of the risk management process, i.e. risk analysis, risk evaluation, risk control and postproduction information, are generally documented in a risk management file. This risk management file is required prior to product launch to get FDA approval to bring a medical device to market. Using the risk management process outlined in ISO 14971 standard as a guideline to manage risk can ensure the design and deployment of a safe product, with an acceptable level of risk. This process can be applied to non-medical fields as well. While this thesis investigates the application of risk management processes at a system-level as opposed to the product-level, the relationship between system-level and product-level risk should be considered. [13]

Figure 4. The ISO 14971 standard risk management process [7]
One feature missing from the risk management processes described in this section is a link to timing and cadence. While the ISO 31000 process suggests periodic or event-triggered monitoring and review, it does not include guidelines for how long the period should be. Additionally, neither process incorporates guidelines for when to identify risks (whether periodic or event-triggered identification) or when risk management should begin for a project.

*Risk Register*

A risk register serves as a centralized database for organizations to track, monitor, and reduce risks. A risk register can be used to manage risks identified both during initial safety assessments and during ongoing operations [14]. Risk registers are used in a variety of industries, including medical. Cooke-Davies (2002) found that the adequacy with which a visible risk register was maintained was one of the key success factors for project management [15]. Patterson and Neailey (2002) highlight the importance of the risk register as a method to enable all stakeholders to “consciously evaluate and manage the risks as part of a decision making process” [16]. Figure 5 shows the results from a study done by M.C. Leva et al (2017) on the benefits of risk registers [17]. The most important functions include data trending of risks, facilitating risk reporting to senior management, and communicating the risk management process.
Figure 5. The benefits of using risk registers to record risks [17]

However, Kutsch and Hall (2010) warn of the danger of risk registers becoming ‘tick-box’
exercises when the owners and contributors do not have a real ability to influence the risks [18].
Other potential concerns regarding risk registers include the failure to account for “unknown
unknowns”, too many risks listed that become hard to prioritize, individual and ad hoc
consideration of events instead of system-level consideration, and its static nature. Despite the
widespread use of risk registers in industry and their benefits, there is very little guidance on
their development and implementation. [19]

2.4. Systemic Risk Approaches

In complex systems, risk causality includes more complex causes than single-point or chain-of-
event failures. A systems-thinking approach is required to identify factors that indirectly
contribute to risk level. This research builds on the System-Theoretic Accident Model and
Processes (STAMP) and leading safety indicators approach [20] as well as the Risk Driver model
developed by Dr. Retsef Levi at MIT.
2.4.1. Leading Indicators and STAMP

Leveson (2015) proposes a method of prospective risk avoidance in the form of an approach to identify leading indicators for safety risks. This approach is based on the System-Theoretic Accident Model and Processes (STAMP), which is a model of accident causation that includes non-linear and indirect relationships and is based on systems theory rather than reliability theory. Like the Risk Driver model, the motivation for the use of leading indicators is a belief that major risk events do not result only from a set of proximal, physical events but from an organizational environment that has shifted to a heightened state of risk over time. This shift occurs as a result of safeguards and controls being relaxed over time due to conflicting goals and tradeoffs. [20]

2.4.2. Risk Driver Model

The Risk Driver model (Figure 6) describes the impact of risk event and outcome drivers on the uncertainty surrounding a risk event and its potential outcome, respectively. Risk drivers are defined as general conditions of the system, stakeholders, and environments that contribute to a heightened state of risk. This model is based on the widely accepted definition of risk as the severity of an event combined with the probability that the event will occur [20]. The model also employs the following terms to describe certain key aspects: Risk Events, Risk Outcomes, Risk (or Event) Drivers, and Outcome Drivers. These terms are defined as follows:

- Risk Event: the specific uncertain event that might occur
- Risk Outcome: the potential outcome(s) that will result if the risk event does occur
- Risk/Event Drivers: conditions of the environment, the system and the people in the system, that affect the likelihood of the risk event to occur
- Outcome Drivers: conditions of the environment, the system and the people in the system, that affect the magnitude of the outcome of the risk event if it indeed occurred [21]
Yiqun Hu (2017) uses a car accident as an example to illustrate the concepts of Event Drivers and Outcome Drivers:

“In general, a specific accident could be due to a variety of direct reasons such as loss of control of vehicle, failure to stop or the existence of foreign object on the road. Event drivers in this case could be road conditions, badly maintained car or tired driver. These are examples of event drivers related to the condition of the environment, the system, and the people in the system, respectively, which increase the likelihood of a car accident to occur. On the other hand, lack of safety features in the car could affect the magnitude of the injury from the crash, and is considered as an outcome driver.” [21]

Risk driver analysis is distinct from root cause analysis. The root cause of an event is an initiating cause of either a condition or a causal chain that leads to an outcome or effect of interest [21]. The Risk Driver model is based on the assumption that there are relatively few risk drivers which are common to many risk events in a given system [22]. By eliminating and monitoring risk drivers, it is possible to reduce the likelihood of a variety of risk events simultaneously [21].

The existing literature on the Risk Driver model applies it in a hospital environment, but there are opportunities to apply this model in other industries. Additionally, both Traina and Hu use the Risk Driver model to analyze risk events that have already occurred. Hu identifies a
prospective approach to use current information to predict future risks as an opportunity for future work.

2.5. Principles as a Foundation for Frameworks

Basic principles and concepts of risk management can establish a foundation for risk management tools and frameworks. Olechowski et al (2016) propose that the eleven ISO 31000 principles should be used as an alternative to more rigid standardization. Uzulans (2016) claims that the correct use of the definition of risk and risk management concepts can promote the development of project risk management documents [23]. Building a foundation based on principles can foster an improved shared understanding of risk management best practices. [5]

2.6. Chapter Summary

The literature cited in this chapter discusses existing industry standards for risk management and their commonalities, as well as common tools and frameworks that are used in research and industry to enable effective risk management. There is a general consensus around the aspects of the risk management process, but researchers have raised questions around how effectively these theoretical procedures can be translated into practice. Additionally, the Risk Driver model has been proven to be effective in identifying risk drivers based on risk events that have occurred, but the Risk Driver model may be used to prospectively reduce risk. Existing literature posits that a strong understanding of risk management fundamentals may promote improved practices over simply repeating the steps of the established processes. The work done as part of this thesis investigates the implementation of the risk management process at a specific contract manufacturing company. The company’s level of engagement in different practices is evaluated empirically. It explores how tools and frameworks can be used to build a foundation for risk management based on fundamental principles.
3 Current State of Risk Management at Flex

3.1. Introduction

At the initiation of this project, there were no standard processes at Flex for project risk management that were consistently applied, even only within the HRS organization or the Health Solutions group. Some individual factory sites or teams did have defined project risk management processes, tools, and practices, but these were generally not shared with other sites and teams. Flex did have some established standards for other areas of risk management, such as contract and inventory risk management. This chapter discusses the methodology used to evaluate the current state of risk management in HRS and the resulting insights. The current state was evaluated both for the CGM Program specifically and also at the broader organization level.

3.2. The CGM Program

As mentioned in Chapter 1, Flex has recently begun production development on a new program to make continuous glucose monitors (CGMs) for one of their largest customers in the medical device industry. Due to the high risk-level, urgency, and new technical aspects of the program, it was chosen as the focus for this research project to identify areas for risk management improvement and to pilot new processes and tools. In 2015, Flex won the contract to produce this CGM product in the United States. After several years of delays, development began at one of Flex’s sites in the Chicago area in January 2018. The site is relatively new compared to some of Flex’s other factories—it was purchased by Flex approximately 5 years ago and was originally used to produce precision plastic parts. The CGM Program requires significant investment in structural additions to the factory, including the installation of steel mezzanine levels and a concrete sterilization bunker, as well as specialized machinery and equipment. The customer and Flex’s management have prioritized launching the program as quickly as possible in order to meet patient needs. The target date to start producing sellable units is in the fall of 2019.

The program management team for the CGM Program is led by the Director of Program Management, who is responsible for the overall program delivery as well as presenting out at a high-level to both senior management and in customer-facing meetings. He is supported by the
lead Program Manager (PM), who is responsible for managing various day-to-day activities such as tracking action items and team meetings. The lead PM is also responsible for understanding the technical details of the end-to-end production process. Both the Director of Program Management and the lead PM are supported by a team of PMs that are each responsible for one of the key functional areas of the project. The functional areas include Automation, Sterilization, Facilities, Surface Mount Technology (SMT), Conveyor, Molding, IT, and Quality Systems.

3.3. Research Approach

The current state of project risk management practices in the HRS organization was assessed by evaluating the existing initiatives and tools related to risk management that are deployed across HRS at the corporate level, as well as the risk management practices currently in use on the CGM Program. At the organizational level, the current state of risk management standardization was assessed by interviewing key stakeholders on the Global Program Management and Strategy teams. For the CGM Program, this involved interviewing the program management team and reviewing the risk management data. The data came from two primary sources: Excel files used for logging identified risks and an online program management tool.

3.4. Organizational-Level Assessment

Several initiatives related to project risk management were ongoing within HRS at the corporate level at the time of the current state assessment. They include SHIELD, an online program management tool that includes risk-tracking functionality, the Medical PM 2.0 initiative, which established a new program manager role specifically for medical-related programs whose responsibilities would include end-to-end project risk management, and PM Prime, a new online training program for Flex program managers.

3.4.1. SHIELD

The “Simplified Handshake to Inform, Execute, Launch, and Deliver”, or SHIELD, is an online program management tool that was developed “in-house” by the HRS Global Program Management team. The initial purpose for the tool was to give executive leaders real-time visibility into the financial information and status of the ongoing HRS programs across the
different Flex sites and to the facilitate the hand-off of projects from the commercial team (which negotiates the initial business proposal) to the factory team. SHIELD also provides a centralized location to record and update information related to each program from the initial planning phase through mass production. It also serves as a database for program data and as a form of standardization for program management practices across different programs. SHIELD usage was mandated for all HRS programs, but adoption levels remained low. Users complained that the tool was frustrating to use because of its unintuitive user interface and slow response time. PMs preferred to use tools that they were familiar with, such as Microsoft Project, Excel, and PowerPoint. Even some executive leaders, for whom the tool was originally created, did not regularly reference the data in SHIELD.

One of SHIELD’s key features is a program homepage that has tabs for different program trackers, including a Risk Register (for design and manufacturing), an Action Tracker, and Milestone Trackers. These tabs are updated by the program managers from program kick-off through mass production. The format of the SHIELD Risk Register is shown in Figure 8. It includes fields for a risk description, drop-down selections of High, Medium, or Low for risk probability and impact, and a field for a description of the risk response plan. The definitions of High, Medium, and Low probability and impact ratings as defined within the SHIELD tool are as follows:

- **Low Probability:** Unlikely to occur, but could
- **Medium Probability:** May occur
- **High Probability:** Likely to occur
- **Low Impact:** Minor impact on the project, and would create minor customer dissatisfaction
- **Moderate Impact:** Moderate impact on the project, and would create customer dissatisfaction
- **High Impact:** Major impact on the project, and would create significant customer dissatisfaction

One failure of these definitions is the lack of specificity and associated quantification, such as a percentage range assigned for each probability level. Another disadvantage of generalizing the
definition of low, moderate, and high probability level is the failure to involve any group
discussion of the underlying assumptions on which the probabilities are based. This could lead to
differing interpretations of the risk levels across team members and misunderstanding of the true
risk level. The matrix that defines the priority level for each risk based on the probability and
impact rating is shown in Figure 7. The SHIELD tool is programmed so that a person entering a
risk can select the probability and impact ratings from a drop-down menu, and the tool
automatically assigns a priority based on the matrix.

Figure 7. Risk priority matrix in SHIELD based on probability and impact

While these are common features of risk register templates, the SHIELD risk register also
includes additional functionality. For example, every time a change is made to a risk entry in the
tool, the time and person making the edits is recorded and can be referred to later.

Figure 8. SHIELD Risk Register entry fields
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As a risk management tool, SHIELD could be confusing for users. PMs who had been using the tool reported that they used the Risk Register to log both risks and issues, since there was no Issue Log feature built into SHIELD. A PM in the Automotive group, which had a higher rate of SHIELD adoption than the Health Solutions group, commented that typically only 5-10 risks would be tracked in the risk registers at a time for smaller programs. As a result, very little time was spent focusing on risk management.

3.4.2. Medical PM 2.0

The HRS Corporate Strategy team is leading an initiative called “Medical PM 2.0” to create a new Global Technical Program Manager (GTPM) role for high volume, highly technical medical programs. This initiative was driven by the need for improved continuity across the different phases of a program, from bidding for the contract to project scoping to development. In order to define the responsibilities for this new role, the Corporate Strategy team interviewed experienced PMs across Flex’s different organizations and sites to identify existing gaps and potential opportunities. Figure 9 shows the current state of program management roles and responsibilities as determined by this assessment. The key program deliverables (listed in the horizontal categories) are distributed across multiple different individual roles over the end-to-end life of a program (listed in the vertical categories), including the Global Account Manager (GAM), Design PM, NPI PM, and Site PM. The chart in Figure 9 shows which roles are either owners or contributors for each key program deliverable. Risk management responsibilities are a subset of key program deliverables and are represented in Figure 9 by the “Risk and scope change mgmt” category, which is defined as robust assessment of risks and balancing tradeoffs between budget, schedule, and quality. Feedback from the PMs surveyed indicated that the distributed accountability and hand-offs between different owners led to ineffective assessment of risks and tradeoffs. This failure to effectively assess program risks ultimately compromised the program schedule, as well as product cost and quality.
Figure 9. Current state of HRS program management roles and responsibilities

Figure 10 shows the same roles and responsibilities table as Figure 10 but with the addition of the GTPM role. One of the key changes made is the centralization of ownership for all end-to-end program risk management responsibilities to the GTPM.
### Legend: Key Program Deliverables & Roles Required

<table>
<thead>
<tr>
<th>Owner: Drives critical tasks</th>
<th>Contributor: Supports / provides input</th>
</tr>
</thead>
<tbody>
<tr>
<td>End-to-End</td>
<td></td>
</tr>
<tr>
<td>Risk &amp; scope change mgmt↑</td>
<td></td>
</tr>
<tr>
<td>Track handoffs in SHIELD</td>
<td></td>
</tr>
<tr>
<td>Synchronized customer updates</td>
<td></td>
</tr>
<tr>
<td>Proposal / RFQ</td>
<td></td>
</tr>
<tr>
<td>Customer requirements</td>
<td></td>
</tr>
<tr>
<td>Capability assessment</td>
<td></td>
</tr>
<tr>
<td>RFQ</td>
<td></td>
</tr>
<tr>
<td>Design</td>
<td></td>
</tr>
<tr>
<td>Product design &amp; DFX</td>
<td></td>
</tr>
<tr>
<td>Supply chain design</td>
<td></td>
</tr>
<tr>
<td>NPI</td>
<td></td>
</tr>
<tr>
<td>Design verification &amp; builds</td>
<td></td>
</tr>
<tr>
<td>Process development</td>
<td></td>
</tr>
<tr>
<td>Equipment sourcing &amp; design</td>
<td></td>
</tr>
<tr>
<td>Mass Production</td>
<td></td>
</tr>
<tr>
<td>Process validation &amp; ramp</td>
<td></td>
</tr>
<tr>
<td>Operations &amp; CFT coordination</td>
<td></td>
</tr>
<tr>
<td>Claim identification &amp; recovery</td>
<td></td>
</tr>
</tbody>
</table>

Figure 10. Proposed GTPM program management roles and responsibilities

3.4.3. PM Prime

At Flex’s factory sites, training programs are primarily developed and administrated by a Site Training Coordinator. Flex also develops company-wide trainings at the corporate level for subject areas that require or are suited to a higher level of standardization. Flex recently initiated an overhaul of internal program management training resources. The PM Prime training program was developed as part of this initiative. It provides a training roadmap (Figure 11) and materials related to fundamentals of program management, including risk management. The Risk Management training module is outlined in red in Figure 11. This module occurs late in the training program and is intended only for advanced project managers. It mostly pertains to risk management for contracts and non-disclosure agreements; while these subjects are related to project risk management, the training program fails to explicitly present project risk management concepts.
3.4.4. Integration of Tools and Initiatives

The existing state of project risk management within HRS prior to the start of this project was defined by a series of disjointed initiatives. The Medical PM 2.0, PM Prime, and SHIELD initiatives were driving change to the respective people, processes, and tools involved in risk management. The initiatives were being managed by different organizational groups with little to no integration. Additionally, the focus of these initiatives is much broader than project risk management. As a result, their treatment of risk management is somewhat superficial and lacks a basis in the fundamentals of risk and risk management. Another consequence of the lack of integration of these risk management initiatives is that they may inhibit an integrated, end-to-end risk management process and organizational awareness of inter-dependencies. The lack of standardization of tools and processes across phases prevents knowledge transfer. For example, the initial risk assessment done before the start production development for the CGM Program was lost due to team member changes and a lack of a standardized procedure to record it. The Medical PM 2.0 initiative seeks to create continuity by consolidating ownership of risk
management across phases. SHIELD creates a common tool and accessible record to facilitate the transfer of information. Training is needed to ensure that all stakeholders have a common understanding of the process and language to communicate risks. Although these activities have a common goal, a framework is needed to integrate them together. Figure 12 depicts where the current risk management tools and initiatives in development at Flex could be incorporated to bridge gaps in risk management hand-offs between each program phase.

Figure 12. Opportunities to incorporate new risk management tools and initiatives

3.5. CGM Program Assessment

At the CGM Program-level, it was found that the program management team did not have a consistent understanding of the risk management processes or concepts. Site leadership had not established expectations for what tools should be used for risk management. Most of the functional area PMs were using an Excel risk register template (see Appendix 1) to register and track program risks. The template included an overview of Project Risk Management, guidelines for risk assessment and rating, and instructions with examples for how to identify and respond to potential risks. There was no set cadence for how often the risk registers should be updated, so some had been updated on a weekly basis while others were only occasionally updated. Some PMs were not tracking risks at all. The risks for each functional area were tracked in separate Excel files, and there was no document that compiled all of the program risks into one spreadsheet.
Distinguishing between Risks and Issues

Many of the risks that were recorded in the Excel risk registers were either not clearly defined or more appropriately categorized as issues, problems, or action items. Some examples are shown in Figure 13. The risk register template did not provide any guidance on how to define risks. Also notable was the lack of any type of documentation or log for program issues. As a result, the risk registers were being used by the PMs as a de facto issue log without any differentiation between issues and risks.

<table>
<thead>
<tr>
<th>Risk Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cell 2 assembly behind 2 weeks</td>
</tr>
<tr>
<td>Availability of molded components to support validation.</td>
</tr>
<tr>
<td>Lab is not adequately staffed in a timely manner to handle validation and data handling.</td>
</tr>
<tr>
<td>Need requirements and timeline for the conveyor belt Solution</td>
</tr>
</tbody>
</table>

Figure 13. Examples of non-risk entries in CGM Program risk registers

Integration into Overall Program Management Activities

Other ongoing program management activities included action tracking, schedule management, resource allocation, and status reports. At the time, most of these activities were managed in separate documents by different people. For example, the lead PM tracked action items for the overall program in an Excel spreadsheet and reviewed it once a week with the functional area PMs. The overall schedule for the program was developed in Microsoft Project by an external contractor supporting the PM team. Weekly status reports were typically created and presented as PowerPoint slides by the different functional area PMs. The HRS group at Flex had internally developed a custom online program management tool, SHIELD, which was designed to integrate these activities into one place. Although the CGM Program team had initially started out using this tool, they found it to be frustrating to use and lacking certain necessary features that other tools provided. Figure 14 shows the activity in the SHIELD Risk Register from January to June 2018. During this time period, interactions with the tool are characterized by sharp spikes when many updates are made in a short period of time (primarily by one person), as well as several periods of little to no usage. Explanations for why these spikes may occur include after a meeting.
during which risks were discussed and after managers had instructed the team to update risks in the tool.

![Risks Modified in SHIELD (Jan - Jun 2018)](image)

**Figure 14.** Risk entry modifications made between January and June of 2018

### 3.6. Chapter Summary

At the time of the current state assessment, Flex did not have any standard processes for project risk management that were consistently applied across the company, or even only within HRS. At the organizational level, the SHIELD and Medical 2.0 PM initiatives revealed that Flex has identified a lack of standardization of risk management tools and processes that is preventing knowledge transfer through the end-to-end life of a program. Additionally, it was found that the distributed accountability and hand-offs between different owners led to ineffective assessment of risks and tradeoffs. On the CGM Program, there was not a clear standard for how risks should be documented or a common understanding of the definition of risk, which led to ineffective and inconsistent risk management practices. The failure to effectively assess program risks highlights a gap of common language and frameworks to communicate and discuss risks across the
organization. The next chapter discusses the approach taken to establish improved risk management practices through the use of frameworks.
4 Application of Risk Management Frameworks

4.1. Introduction

This research applies several different frameworks for project risk management to Flex’s CGM Program. These frameworks are incorporated into interventions during a pilot study as well as for additional analysis to derive systemic risk insights. Although the pilot focuses on project risk management for medical device manufacturing in the production development phase, these frameworks are intended to be applicable across other production phases and industries. This chapter describes the different types of risk management frameworks used and how they are applied to risk management practices both during the pilot program and afterwards for additional analysis.

4.2. Pilot Study Approach

The approach taken to implement improvements to project risk management practices for the CGM Program pilot study is outlined in this chapter. The “pilot study” is defined as a sustained engagement over a period of 6 months, during which several interventions were implemented and evaluated with the goal of improving project risk management practices in use on the CGM Program. The approach has four key elements:

1. Establishing functional definitions for risk management concepts
2. Using frameworks to clarify risk management fundamentals
3. Assigning a “Champion” for risk management
4. Communicating best practices to stakeholders

Each element of the approach serves a different purpose. The “Champion” for risk management initiates and helps to drive the change management process. Frameworks are used to create clarity around the new concepts that are introduced and facilitate a common understanding across stakeholders. It is also essential to effectively communicate the improved practices to the relevant stakeholders in order to ensure that they are sustainable.
4.2.1. Pilot Study Timeline

The CGM Program pilot study took place over a period of 6 months, starting at the end of June 2018. The different phases of the pilot study are outlined below.

- **Current State Assessment**: the “Champion” for risk management is introduced to the CGM Program team and spends 2 weeks on site evaluating the current state of project risk management practices, including what tools and processes were in use.

- **First Risk Workshop**: the first Risk Workshop took place on July 26, approximately one month after the start of the pilot study. The first Risk Workshop introduced fundamental risk management concepts, such as the difference between risks and issues and how to rate the likelihood and impact of a risk. During the workshop, frameworks such as process flow diagrams and decision protocols were used to illustrate these concepts.

- **Transition to SHIELD Risk Register**: During the first 2 weeks of August, the “Champion” for risk management led an initiative to transition all of the risks captured in separate Excel risk registers to the risk register in SHIELD. This involved meeting with each functional area program manager and technical lead to review the existing risks and to update them or add new risks as necessary. The “Champion” for risk management also helped the team members apply guidance from the first Risk Workshop to write risk descriptions and response plans.

- **Second Risk Workshop**: the second Risk Workshop took place on August 21, approximately one month after the first Risk Workshop. During this workshop, the team reviewed the risk management concepts and process presented in the first Risk Workshop and aligned on the highest priority overall risks for the program. The team was also trained on how to use the SHIELD tool to record risks and the expected cadence of when risks should be reviewed and updated. An evaluation survey was sent out after this workshop in order to assess the team’s understanding of risk management concepts and activities.

- **Period of No Intervention**: From the beginning of September to mid-November, a period of two and a half months, the CGM Program team was allowed to use the risk management process and SHIELD tool without involvement of the “Champion” for risk management. The purpose of this period of no intervention was to evaluate whether the best practices established in the workshops were sustainable and effective for the team.
• **Final Risk Check-ups**: At the end of November, the “Champion” for risk management scheduled follow-up meetings with each functional area program manager and technical lead in order to ensure that the risks recorded in SHIELD were still up to date. A final evaluation survey was sent out at this time to assess the overall effectiveness of the pilot study.

### 4.2.2. Defining Risk Management

Risk management is a broad subject that can apply to a variety of more specific sub-categories. In the manufacturing industry, risk management is often referred to in the context of supply chain risk management or Process Failure Mode Effects Analysis (PFMEA). The International Organization for Standards (ISO) also provides guidelines for risk management for project management and medical applications in ISO 31000 and ISO 14971. ISO 31000 defines risk as “the effect of uncertainty on outcomes”. While the different aspects of risk management are interrelated, this research focuses specifically on “project risk management”. Project risk management is defined by T. Williams (1995) as a field of project management that seeks to analyze and manage the uncertainties and risks surrounding projects to enable managers to achieve their objectives. These definitions emphasize that uncertainty is an essential and fundamental aspect of risk; however, as noted above, many people struggle with this concept in practical application. These four terms are defined within the context of the thesis as the following:

**Concerns**

The word “concern” is defined by the Merriam-Webster dictionary [24] as “a matter that causes feelings of unease, uncertainty, or apprehension.” For the purposes of this project, “concern” is used as a label for ideas that have not yet been sufficiently defined to be classified as risks, issues, or problems.

**Risks**

Since the focus of this research is project risk management, as opposed to other areas of risk management, the definition of risk as defined by the Project Management Institute’s Project Management Body of Knowledge (PMBOK) Guide is used. The PMBOK defines risk as “an uncertain event that, if it occurs, has a positive or negative effect on a project’s objectives.” [25]
Issues
The PMBOK Guide defines issues as “an event that has already happened and has impacted or is currently impacting project objectives” [25]. In the pilot study approach, the definition of an issue is expanded to include events that have not yet occurred, but are certain or almost certain to occur.

Problems
Within the context of this project, a problem is defined as an event that has already happened, or has not yet happened but is certain to occur, that negatively impacts project objectives and requires actions to mitigate impact.

4.2.3. Applying Frameworks
Frameworks are used to clarify the following fundamental concepts of project risk management: (i) the definition of risk, (ii) the risk management process, and (iii) how risk management fits into overall project management. Although most project managers are aware of risk management concepts, it can be difficult to translate them to real-world processes and methodologies [8]. Simple frameworks can be used to clarify how these concepts are applied. Three frameworks were applied during the CGM Program pilot study: (i) process flow mapping, (ii) the Risk Driver framework, and (iii) decision protocols and are used to facilitate several different interventions. The risk driver model and decision protocols establish clear definitions for risk management concepts and introduce risk management frameworks. Useable processes that ensure adherence are established through process mapping and the pilot study. The Risk Driver Model and data generated by Flex’s risk management tools are used for risk driver analysis to derive insights.

Process Flow Mapping
Process flow mapping is traditionally used in the chemical or manufacturing industries to describe the flow of plant processes, materials, and equipment. The risk management process can also be illustrated with flow diagrams. Using a flow diagram for this application helps clarify the sequence and relationship between each step of the risk management process.

The project risk management process flow diagram developed for the CGM Program (Figure 15) is based on the ISO and PMBOK process standards. The flow diagram illustrates the
relationships between each step of the risk management process, but it also includes some additional features for improved clarity. For example, an orange rhombus represents each point in the process where a key decision needs to be made. A SHIELD symbol is attached to the process steps that require an update in the SHIELD Risk Register. The "stop sign" symbols represent where the risk management process ends, such as when a risk is retired or when it is triggered and subsequently transferred to the Issue Log for continued management. This process flow diagram was used in both Risk Workshops to communicate the process to CGM Program team members.

Figure 15. The CGM Program project risk management process flow diagram

Risk Driver Framework

The Risk Driver framework can be used to clarify the distinctions between risk events and risk outcomes, as well as the role of uncertainty in both risk events and outcomes. As discussed in Chapter 2, a risk event is defined as the specific uncertain risk, and a risk outcome is the potential outcome(s) that will result if the risk event does occur. A phenomenon that can cause confusion when managing risks is that when outcomes are uncertain, they can turn into risks, which then spawn a chain of new risks (Figure 16). The Risk Driver model (Figure 17) simplifies this system into three factors for each risk: (1) the risk driver, (2) the risk event, and (3) the risk outcome. Limiting the scope of the risk in this way facilitates analysis of the risk and illustrates how uncertainty fits into this system. The Risk Driver model is also used to analyze the data generated by the pilot study, as discussed in Section 4.3.
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Decision Protocols

Frameworks for visualizing protocols have been used in the medical industry to visually depict algorithms or processes that contain primarily conditional control statements in order to assist in quality improvements and reduce process irregularities [26]. In the context of this work, the term “decision protocols” is used to refer to decision support tools that model conditional decisions and their possible consequences. Decision protocols are used in this application to create clarity around the distinctions between risks and issues by highlighting the conditions that differentiate them.

The simplest framework (Figure 18) helps to clarify the concept that risks, issues, and problems often begin as concerns. The most important purpose of this framework is to show that concerns should be articulated and defined in order for them to be escalated and triaged appropriately.
This framework also conveys that risks and issues can at first seem alike without careful definition.

![Figure 18. A simple decision protocol](image)

The decision protocol shown in Figure 19 is a more complex version of the framework shown in Figure 18. It provides a structured process to enable someone to differentiate between a risk, issue, and problem. Although it is derived from the definitions of these three concepts, it articulates the key differentiators as questions to facilitate decision-making.

![Figure 19. A decision protocol for distinguishing between a risk or an issue](image)

The decision protocol in Figure 19 can be extended further (Figure 20) to clarify the relationships between issues with uncertain outcomes and risks. As illustrated in the expanded Risk Driver Model (Figure 16), the outcomes of risks can turn into risk events if they are uncertain. The same can be true for the outcome of issues. Even if an event is certain to occur, it
does not necessarily follow that the outcome of the event will be certain. This can create
confusion around whether an event is a risk or an issue. The concept that risks and issues may
spawn a chain of new risks may also create confusion. The framework in Figure 20 illustrates the
relationship between an uncertain outcome of an issue and risk, which helps provide the structure
necessary to avoid these potential pitfalls.

Figure 20. An expanded decision protocol for distinguishing between a risk or an issue

4.2.4. “Champion” for Risk Management

The role of the “Champion” for risk management is to communicate the priority level and
importance of risk management, as well as to assist in overcoming initial barriers to adoption. In
this case, the “Champion” was an intern from the Leaders for Global Operations program, but it
could be anyone internal or external to the company. One reason for taking the approach of
having a “Champion” for risk management was due to the top-down nature of the initiative. It is
especially important for risk management practices to be driven by organizational leadership
since it is difficult to quantify self-reinforcing positive effects, such as cost savings. The
“Champion” was sponsored by the President for Health Solutions and the President of HRS at
Flex, which helped convey the priority of the project to the CGM Program team members. The
“Champion” was responsible for communicating the importance of risk management practices to key stakeholders and the CGM team through a series of workshops and one-on-one meetings.

Adoption Barriers

Another critical role of the “Champion” for risk management is to help the participants in the pilot program overcome barriers to adoption of improved risk management practices. One area where the “Champion” was able to overcome adoption barriers in the pilot was the adoption of the online Risk Register in SHIELD. Although use of SHIELD had been mandated by corporate and site management, the risk register had only been updated on 11 different days from January to December (Figure 14). The PM’s working on the CGM Program had started using their own Excel risk registers, and only some of them had been trained on how to use the SHIELD tool. The “Champion” for risk management was able to compile all of the different Excel risk registers and transfer each risk into SHIELD, as well as show each individual PM how to log into and use the tool. This shifted the extra workload of transferring risks and finding training resources from the PMs and ensured that the SHIELD Risk Register was complete and ready to use at the time of adoption.

The “Champion” for risk management also helped participants in the pilot study to overcome adoption barriers by developing training materials. Training was needed to give the members of the CGM Program team a common understanding of project risk management basics as quickly as possible. At the time, the HRS group did not have any up-to-date internal training programs specifically dedicated to the topic of project risk management. In order to expedite the training, the materials were co-developed internally by the “Champion” for risk management and the Director of Program Management of the CGM Program instead of seeking an appropriate training package developed by a third party. This also allowed for the project risk management training to be tailored to the CGM Program for the purposes of the pilot study.

4.2.5. Communicating Changes and Educating Team Members

A key element of the pilot study approach is educating team members about project risk management concepts and best practices as well as communicating changes made as part of the improvement process. To accomplish both of these objectives, the “Champion” for risk management and the Director of Program Management for the CGM Program developed two
customized workshops. The attendees included all of the PM’s working on the CGM Program, as well as the technical leads for the different functional areas.

*Workshop 1*

The first workshop occurred approximately one month after the start of the pilot study program, once the current state of project risk management had been evaluated. It focused on clarifying the definition of risk, team member’s roles related to project risk management, the risk management process, and expectations for the frequency of risk review. The workshop also included a risk identification and assessment activity to allow team members to apply the concepts.

*Workshop 2*

The second workshop took place one month after the first workshop. The primary objectives of the second workshop are listed below.

1. Process for reviewing, updating, managing risks, reporting risks is understood
2. Process for using SHIELD tool to track risks is understood by team
3. Highest priority program risks have been vetted and consensus reached by team
4. Team has common understanding of how to plan a risk response

The purpose of the first objective was to reinforce the learnings from the first workshop and to improve upon some of the content. For example, the risk management process flow from the first workshop was improved for the second workshop based on feedback from team members. The second objective focused on how to use the SHIELD Risk Register, with the intention that it would become the primary risk register for the CGM Program following the workshop. The third objective of the workshop was to spend time reviewing the highest priority risks for the program. Up until then, all risks had been tracked separately by the different PM’s working on the program, and there was no up-to-date register of all program risks. Reviewing them during the workshop enabled the team to reach a common understanding of the program’s highest risk management priorities and of the relative priority of different risks. The final objective was met by allowing the workshop attendees to work in small groups to create risk response plans for 1-2 top risks based on guidelines provided (Figure 21).
4.3. Risk Driver Analysis Methodology

In 2018, over one hundred individual risks were identified and recorded for the CGM Program. Using the Risk Driver model, these risks can be analyzed in aggregate to identify some of the conditions, or risk drivers, of the CGM Program that are driving the uncertainty behind these risks. The determined risk drivers are evaluated to identify trends and commonalities. These trends can inform program management decision-making to ensure that these underlying conditions are monitored and addressed as part of overall risk management.

4.3.1. Risk Driver Model

The concept of Risk Drivers is discussed in Chapter 2 of this thesis. The Risk Driver model (Figure 22) describes the relationship of the Risk and Outcome Drivers of Risk Events and Outcomes. Risk Drivers are used to describe and assess the structure of the uncertainty underlying the Risk Event, and Outcome Drivers relate in a similar manner to the potential outcome. This analysis applies the Risk Driver model to the risks identified for the CGM Program, with a specific focus on Risk Drivers and Risk Events only.
4.3.2. Risk Driver Identification

Existing literature on the Risk Driver model describes its application to the environment of a hospital Intensive Care Unit (ICU). A study by J. A. Traina (2015) takes a retrospective approach to Risk Driver analysis. The risk driver identification process used began with a review of 20 serious adverse events reported from Beth Israel Deaconess Medical Center’s ICUs. A team of external and internal experts at the hospital reviewed each case in depth to identify risk drivers or conditions among the staff, ICU unit, or broader organization that may have contributed to the event. In the case of the CGM Program, the majority of the events were analyzed before occurrence, i.e., while they were still uncertain risks. The data set includes both open and closed risks. Additionally, they were reviewed only by the “Champion” for risk management, who had both an intimate knowledge of the CGM Program risks as well as an understanding of the Risk Driver framework. This approach was taken due to the large quantity of risks reviewed. To determine which risk drivers applied to each risk, the risk description and additional contextual notes recorded in the SHIELD tool by various CGM Program team members were assessed individually by the “Champion” for risk management. [21] [22]

4.3.3. Risk Driver Analysis

The analysis performed on the identified risk drivers involves determining which common risk drivers across multiple risk events had the highest frequency of occurrence. Insights derived from this analysis can inform to targeted actions that Flex could take to address these common risk drivers. By identifying and addressing the most common risk drivers, Flex may be able to reduce the likelihood or impact of a broad range of risks. The results of this analysis are discussed in Chapter 6.

Figure 22. The Risk Driver Model
4.4. Chapter Summary

The frameworks discussed in this chapter are used in two different ways: (i) to add structure to risk management interventions made during the CGM Program pilot study, and (ii) to generate insights related to systemic risk from follow-up analysis. The pilot study approach has four key elements: defining risk management concepts, using frameworks to clarify concepts, a “Champion” for risk management, and communicating improved practices. The systemic risk approach applies the Risk Driver model to risk data generated during the pilot study to assess the system conditions that may contribute to a heightened state of risk on the CGM Program. The results of the pilot study and Risk Driver analysis are discussed in Chapters 5 and 6, respectively.
5 Pilot Study Results

5.1. Evaluation Criteria

The evaluation of the CGM Program pilot study consists of the following criteria:

1. The effectiveness of the interventions
2. The adoption level of processes and tools introduced during the pilot
3. The prospects for long-term sustainability of risk management practices on the CGM Program

The key interventions made during the pilot study were risk management training workshops and the appointment of a “Champion” for risk management. The purpose of implementing these interventions was to improve risk management best practices on the CGM Program that were based in fundamental principles and sustainable in the long-term. These interventions incorporated several different risk management frameworks, as discussed in Chapter 4. By assessing the effectiveness of these interventions and their impact on the likelihood of long-term sustainability, it is possible to indirectly evaluate whether the CGM Program team’s understanding of fundamental risk management concepts was improved.

The primary purpose of evaluating these aspects of the pilot study is to provide recommendations for future risk management pilot implementations on other Flex programs. The processes and tools implemented as part of the pilot study project risk management improvements are described in Chapters 3 and 4. The adoption levels of these processes and tools are evaluated to assess their overall utility to the CGM Program team and their understanding of the risk management process. The likelihood that the risk management practices introduced to the CGM Program will be sustainable in the long-term is assessed by evaluating which individuals are engaging with the tools and whether the team has a good understanding of the fundamental principles.
5.2. Evaluation Methodology

Two primary approaches are taken to evaluate the outcome of the CGM Program pilot implementation. The first is to analyze the historical data derived from the Risk Register in the online program management tool, SHIELD. By measuring the team’s adoption of new risk management tools and the consistency of their interactions with the tool, it is possible to draw conclusions about the effectiveness of the “Champion” for risk management in driving change. The evaluation of the data in SHIELD also indicates whether the team was able to successfully apply new risk management concepts. The second approach is to analyze the CGM Program team’s survey responses regarding the training workshops and pilot study. By evaluating the team’s understanding of fundamental risk management concepts, it is possible to determine how effectively best practices were communicated through the use of frameworks. In combination, these methods of analysis are used to help answer the research questions outlined in Chapter 1.

5.2.1. SHIELD Risk Register Historical Data

Once the risk data for the CGM Program was compiled and transferred to the SHIELD Risk Register, all risk tracking activity took place in SHIELD for the duration of the pilot study. One of the functionalities of the SHIELD Risk Register is historical data for all risk entries. Figure 8 shows a SHIELD risk entry. Each entry has a clock icon (Figure 23). A SHIELD user can click on this icon to pull up the entire update history of that particular risk. An example of this page is shown in Figure 24. Each time a risk is added or modified, the time stamp, person who made the change, and risk information is recorded.
Figure 23. The SHIELD historical data traceability function

Figure 24. Example of historical data recorded in SHIELD for Risk ID #1967
All of the Risk Register historical data for the CGM Program, from program kick-off through January 22, 2019, was downloaded from the online tool and compiled into a spreadsheet. Including open and closed risks, a total of 115 individual risk entries for the CGM Program are included for analysis. This data was analyzed to evaluate risk tracking activity and trends over time, including the frequency of use, the types of modifications made to the risk entries over time, and who was using the tool.

5.2.2. Evaluation Surveys

Two anonymous surveys were sent to the pilot study participants over the course of the pilot study. The participants in the pilot study included the CGM Program PM team and technical leads. Out of this group, 9 are PMs and 13 are technical leads. The first survey was sent following the first risk management workshop. The survey had a 40% response rate, with 6 out of 15 surveyed responding. A copy of the survey questions can be found in Appendix 2. The final survey was sent on December 5, 2018 at the conclusion of the pilot study. The survey had a 63% response rate, with 14 out of 22 surveyed responding. A copy of the survey questions is included in Appendix 3. The survey questions asked respondents to evaluate their understanding of key risk management concepts, their ability to execute risk management activities, and the effectiveness of the pilot study interventions.

5.3. Effectiveness of Interventions

Two primary forms of interventions were implemented during the pilot study in order to drive changes to project risk management practices in use for the CGM Program. As discussed in Section 4.2, the first intervention was to assign a “Champion” for project risk management to drive change and help the CGM Program team overcome adoption barriers. The second major form of intervention was a series of training workshops on project risk management practices, which were based on the frameworks discussed in Chapter 4. The effectiveness of these interventions based on the results of the pilot study are discussed in the following section.

5.3.1. “Champion” for Project Risk Management
Figure 25 shows the interventions of the “Champion” for project risk management overlayed with the activity in the SHIELD Risk Register. Between points A and B, there is almost no activity. Although the adoption of the tool had been mandated by senior management, the CGM Program team was not using the SHIELD Risk Register to track risks during this period from the beginning of June to the beginning of August. Over a period of 1-2 weeks at the beginning of August (labelled C in Figure 25), the “Champion” transitioned all of the program risks from Excel to the SHIELD Risk Register. The shaded “C” area includes around 200 corresponding risk modifications during this period, with the majority of the modifications made by the “Champion”. The second Risk Workshop is labelled point “D” in Figure 25. In this workshop, led by the “Champion” and the Director of Program Management for the CGM Program, the CGM Program team was trained on the use of the SHIELD Risk Register. The period “E” shaded in gray from September to mid-November represents a period when the “Champion” made no modifications to the SHIELD Risk Register. All modifications made during this period were done by various members of the CGM Program team. Another spike occurs at point “F”, when the “Champion” met with functional area PMs and technical leads one-on-one to review and update risks in the SHIELD Risk Register.

These results show that the “Champion” for project risk management was effective at helping to overcome the SHIELD Risk Register adoption barriers. Furthermore, it can be inferred that the SHIELD Risk Register training provided during the 2nd Risk Workshop was effective based on the sustained activity by members of the CGM Program team during period “E”.

Figure 25. CGM Program risk entry modifications over time
5.3.2. Risk Workshops

The first Risk Workshop was focused on basic principles of risk management. An anonymous evaluation survey was distributed to the training attendees to assess its effectiveness. The results are summarized below in Figure 26 and Figure 27. Of those who responded, the reported confidence in the team’s ability to identify and manage program risks increased from an average score of 2.8 to an average score of 3.7 out of 5, with 5 being Very Confident. The CGM Program team’s reported understanding of the risk management process increased by an even greater margin, from an average of 2.5 to an average of 4.2 out of 5, with 5 being a Full Understanding. All respondents agreed that the training clarified roles and responsibilities for risk management and that the training was a good use of the team’s time.

![Confidence in team’s ability to identify and manage program risks](image)

![Understanding of the risk management process](image)

Figure 26. Risk management process understanding before and after the first Risk Workshop.
In the final evaluation survey sent out in December 2018 at the end of the pilot study, one of the questions asked whether the first and second Risk Workshops improved attendees’ understanding of risk management practices and expectations. The breakdown of responses is shown in Figure 28. The majority of those surveyed responded that they Strongly or Somewhat Agreed, with one person responding that they Somewhat Disagreed. These results indicate that while the Workshop training method may have been effective for some people, others might benefit from different forms of training.

The final evaluation survey also asked whether the CGM Program team members were able to sustain the risk management practices presented in the first and second Risk Workshops. The results are shown in Figure 29. The majority of the respondents Somewhat Agreed that the team
was able to sustain risk management practices, while 1 respondent reported that they Strongly Agree, 2 reported that they Neither Agreed nor Disagreed, and 1 responded that they Somewhat Disagreed. These results indicate that some practices were sustained while others were not.

![The CGM Program team was able to sustain the risk management practices presented in the workshops.](image)

Figure 29. Risk management practice sustainability after the workshops

The final evaluation survey asked respondents to provide written feedback and suggestions in response to the question, “Would additional resources, such as another workshop session, 1:1 mentoring, or online training, help improve your understanding of project risk management?” Responses included comments such as “it is always good to have alignment on how the [risk management] process is organized, managed, and communicated” and that online training or smaller group training would be more helpful than another workshop. These results indicate that the Workshops were effective both in the short and long term, although additional training approaches may be required to ensure that risk management practices continue to be maintained.

5.4. Process & Tool Adoption

The adoption of a new project risk management process and Flex’s internally developed online project risk management tool “SHIELD” were key elements of the CGM Program pilot study. The risk management process introduced to the CGM Program team is discussed in detail in Chapter 4, while the SHIELD tool is described in Chapter 3. The adoption levels for each as a result of the pilot study are discussed in the following section, as well as the derived insights.
5.4.1. Project Risk Management Process

Some of the key elements of the risk management process are identifying new risks, assessing risks, treating or responding to risks, and risk monitoring and review [6]. To assess the adoption of the first three elements, respondents to the final evaluation survey were asked to rate their confidence in their ability to identify new risks, to assign a risk rating that is consistent with the team's rating standard, and to determine appropriate risk responses on a scale of Not At All Confident to Very Confident. The response breakdown for each question is shown in Figure 30. Those surveyed were on average most confident in their ability to identify new risks, with only one person responding that they were only Somewhat Confident. The variability in confidence was higher for the ability to rate risks consistently and to determine appropriate risk responses, but still Very Confident on average. It can be inferred from these results that more support should be given to improve the team’s confidence in these areas through aids or additional training.

![Figure 30. The CGM Program team’s assessment of risk management ability](image)

The CGM Program team chose to take a periodic approach to risk review, instead of an event-driven approach. All six PMs that responded to the survey reported that they reviewed risks with their team at least once per week, on average. An additional 4 PMs did not respond to the survey,
but the results indicate that at least half are reviewing risks on a regular basis. This result is particularly important when considered in conjunction with the team’s reported understanding of the difference between risks and issues. Without understanding this distinction, PMs might report that they are reviewing risks when they are in fact reviewing issues facing the program.

5.4.2. SHIELD Tool

All six CGM Program PMs that responded to the final evaluation survey reported that they use SHIELD as well as other tools to track risks. These other tools include weekly reporting formats for Flex management as well as the customer. To assess adoption, the critical period to consider is from the beginning of September to the end of November, during which time the “Champion” for risk management was available as a resource to help CGM Program team members use the SHIELD Risk Register but did not intervene regarding when or how users should be using the tool. Each interaction with the SHIELD Risk Register is tracked in the tool, and this data was analyzed to evaluate trends related to the various forms of interactions. Figure 31 shows the number of new risks added during this period (highlighted in orange), and Figure 32 shows the number of risks that were closed during this period. 13 new risks were added from the period of September to mid-November, with 1-3 risks being added at a time. The addition of new risks is fairly evenly distributed across this period, occurring roughly once a week on average. Twenty-seven risks were closed between September and mid-November. It is expected that more risks would be closed than opened as the project moves forward. Generally 1-4 risks were closed at a time during this period, with one exception of 9 risks closed on Tuesday, October 23, 2018. This outlier may be explained by the fact that the weekly CGM Program review meeting, which involved risk review and included the entire PM team, occurred on Tuesdays.
Figure 31. New CGM Program risks recorded over time
The CGM Program team rated their confidence in their ability to use the SHIELD Risk Register to track risks. The responses (Figure 33) are divided by the role of the responder. This factor is relevant because while all CGM Program team members should be familiar with the SHIELD tool, it is the responsibility of the PMs to actually use and update it on a regular basis. As such, it is expected that the Technical Leads on the CGM Program team would be less comfortable using the tool, which is reflected in the results. However, only half of the PMs who responded reported that they were only Somewhat Confident in their ability to use the tool. The final evaluation survey solicited comments and feedback about the SHIELD tool. One response stated that “SHIELD is not user-friendly”, which may relate to the relatively low level of confidence in using the tool. Some feedback received, such as “SHIELD allows people to raise risks and concerns effectively”, indicated that the SHIELD tool was received positively by the team. Other feedback indicated that there is a need for increased standardization, with one responder stating that SHIELD “needs to be implemented as the single solution for tracking and managing risks.”
5.5. Sustainability of Improved Practices

Long-term sustainability of any changes to practices in an organization can be very challenging to secure, particularly when the change is made over a relatively short period of time. The duration of the CGM Program pilot study was only 6 months, and sustainability of the changes to risk management practices implemented during the pilot will be a measure of its success in the long-term. Three indicators of long-term sustainability are assessed in the following section: Stakeholder Buy-in, Understanding of Fundamental Principles, and Long-term Ownership.

5.5.1. Stakeholder Buy-in

The most important stakeholders for the long-term sustainability of improved risk management practices are the individuals implementing them on a day to day basis, which in this case are the PMs and Technical Leads working on the CGM Program. One way to assess their buy-in is to evaluate the level of engagement with the tools and processes. Figure 34 displays the number of modifications made to risks in the SHIELD Risk Register over the period from September 1 to November 30, 2018. Each color represents a different individual who made the modification, shown in the legend to the right of the bar chart. What is most important to note is that between September 7 and November 24, 8 different stakeholders used the tool. The majority used the tool multiple times over this period. Even without the "Champion" on-site to drive activity, the stakeholders continued to use the tool, which indicates that stakeholders found the tool to be useful in their daily activities.
Figure 34. Engagement with SHIELD Risk Register after interventions

Another indicator that stakeholders found the tools and processes useful is their effectiveness in meeting a critical need for the program. One of these critical needs is the ability for the CGM Program team to be able to communicate and escalate their concerns to management and/or decision-makers. Around one third of responders to the final evaluation survey stated that they Strongly Agree that the risk management process and SHIELD are effective channels to communicate and escalate potential risks and issues (Figure 35). 80% of responders either Strongly Agree or Somewhat Agree; however, the remaining 20% stated that they Neither Agree nor Disagree or that they Somewhat Disagree with this assertion. While this indicates that many of the stakeholders find value in the risk management tools and processes introduced as part of the pilot study, there are still some individuals who are doubtful of the benefits. More work should be done to ensure that the tools and processes are effectively serving all stakeholders.
The conclusion that the majority of stakeholders understand the value of risk management while others are not fully convinced is reinforced by the responses to the final evaluation survey question to “rate your understanding of the value of risk management” (Figure 36). 50% of responders stated that they had a Full Understanding, while the remaining 50% was split between a Fair Understanding and Some Understanding. In general, the CGM Program stakeholder buy-in into the improved risk management practices is fairly strong but likely requires additional reinforcement moving forward in order to sustain practices over time.

5.5.2. Understanding of Fundamental Principles

Another key element of long-term sustainability is the stakeholders’ understanding of the underlying risk management principles and concepts. Without a strong understanding of fundamentals and their importance, stakeholders may revert back to old practices and habits. To evaluate the CGM Program team’s understanding of fundamentals, the final evaluation survey
asked responders to rate their confidence in their ability to distinguish between risks and issues and their understanding of the risk management process. The results are shown in Figure 37 and Figure 38, respectively. The vast majority of team members surveyed felt that they were Very or Extremely Confident in their ability to distinguish between risks and issues, with approximately one third reporting that they were Extremely Confident. The responses regarding their understanding of the risk management process were less positive, with the majority reporting a Fair or Full Understanding. Two people reported that they only had Some Understanding of the Risk Management Process, while one person felt they had Little Understanding. This individual also commented in the survey that they would benefit from “smaller group training” more than a Workshop training session. Further investigation is required to identify optimal approaches to continue to develop understanding of risk management fundamentals.

![Figure 37. The CGM Program team’s ability to distinguish between risks and issues](image)

![Figure 38. The CGM Program team’s understanding of the risk management process](image)

5.5.3. **Long-term Ownership**

A “Champion” for risk management was deployed to drive change and implement improved practices during the CGM Program pilot study, but the “Champion’s” role ended with the
completion of the 6-month pilot. It was therefore necessary to establish long-term ownership for risk management practices in order to sustain the changes made and to continue to improve the process. In order to help ensure long-term continuity, the “Champion” partnered with the Director of Program Management for the CGM Program so that ownership of the risk management improvements was shared by someone permanently assigned to the project. It was also important to partner with this individual since, as the Director of Program Management, he is responsible for developing the program management strategy of his team. Another key stakeholder was the Lead PM for the CGM Program. His role encompasses more of the day to day program management activities for the CGM Program, and so he naturally assumed the role of overseeing updates in the SHIELD Risk Register after implementation in September. Over the period of September to November 2018, approximately 30% of the risk modifications were made by the Lead PM (Figure 34). Involving the Director of Program Management and Lead PM in the development and implementation of improved risk management practices as early as possible will help ensure that they are invested in sustaining the practices following the pilot study.

5.6. Chapter Summary
The results discussed in this chapter answer the research questions related to project risk management frameworks and effective interventions posed by the thesis. They show that establishing fundamental concepts is critical to develop effective project risk management practices, as well as that clear definitions of risk and risk management activities improve understanding of these concepts. Additionally, the results demonstrate that a “Champion” for risk management can drive behavioral change, at least in the near term, by helping to overcome adoption barriers. In-person training programs were also shown to effectively communicate best practices, but they would be improved by supporting resources and engagements. The implications of these results for Flex and other organizations is further discussed in Chapter 7.
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6 Risk Driver Analysis Discussion

6.1. Introduction

In this chapter, the CGM Program risk drivers are analyzed to derive insight into the overall risk level of the CGM Program in production development. As discussed in previous chapters, the CGM Program is highly complex. Not only is Flex producing technically challenging products at a very large scale but also developing a production process that requires specialized equipment and installing it at a relatively new factory site. Normally, project risks are defined as either specific single-point or chains of failures with direct causes or exogenous, catastrophic events that occur almost randomly. The conditions created by the complexity surrounding the CGM Program heighten the overall risk level, but it is difficult to define and target these kinds of indirect risks. The Risk Driver model can be used to help identify these conditions, or risk drivers, and to develop insights that enable Flex to make better-informed risk management decisions.

6.2. Quality of Input Data

It is important to note that the quality of the input data can impact the results of the Risk Driver analysis. In this case, the input data is the individual risk descriptions entered into the SHIELD tool for the CGM Program. It was then up to the “Champion” for risk management, who was familiar with each risk and its context within the program, to determine which risk drivers applied. The quality of the risk descriptions varied significantly based on the when it was entered, the experience of the PM who entered it, and other factors. Three out of 115 risks did not have enough information included in the description to be included in the assessment. Additionally, some of the trends described in the results may be skewed by the behavior of the individuals who are entering the data. For example, PMs who are more comfortable using the SHIELD tool are more likely to enter a higher number of risks related to their functional area than PMs who are less comfortable using the tool.
6.3. Analysis of Common Risk Drivers

A pareto chart (Figure 39) is used to illustrate the observed risk drivers ranked by frequency of occurrence among the CGM Program risks. Since multiple risk drivers could be associated with each individual risk event, there are more observances than the total number of reviewed risks.

![CGM Program Risk Drivers](image)

Figure 39. The frequency of occurrence of risk drivers for the CGM Program

Although the total number of risk drivers is still much less than the number of risks, this analysis focuses only on the top 5 risk drivers: Aggressive Schedule, Highly Cross-Functional Dynamics, Requirements and Standards for Documentation, Knowledge Transfer from Customer, and Lack of Technical and/or Medical Expertise. The definitions of all identified CGM Program risk drivers are listed in Appendix 5. The top five risk drivers are defined in more detail as follows:

- **Aggressive Schedule** describes a condition in which the project timeline—in this case the schedule of milestones between program kick-off and product launch—is truncated to the point that program managers operate under the assumption that there is no buffer in the critical path of the schedule. This philosophy of program management is common to
contract manufacturing, but it incentivizes managers to take extreme measures to recover the schedule when it slips. These measures are often decided and acted upon quickly, which drives risk.

- **Highly Cross-Functional Dynamics** refers to a condition in which often one or more cross-functional areas are dependent on each other for information, materials, or support in order to execute their individual tasks.

- **Requirements and Standards for Documentation** describes a condition in which required documentation and standards either do not exist and need to be produced as a prerequisite to the execution of certain activities or the existing documentation does not meet standards.

- **Knowledge Transfer from Customer** describes a condition in which the stakeholders, in this case the CGM Program team at Flex, are highly dependent on the customer for information that they are unable to obtain themselves for intellectual property, confidentiality, or other reasons.

- **Lack of Technical and/or Medical Experience** describes a condition in which a technical aspect of the program is new to the team, the overall site, the company, or the industry.

These five key risk drivers are analyzed in detail in the subsequent sections. The example risks provided have been edited for clarity and to remove confidential information.

### 6.3.1. Aggressive Schedule

It is not unexpected that the condition of having a very tight schedule would drive risk on any project. In this case, the CGM Program has a very aggressive schedule due to the high market demand for the product, pressure from the customer, the fact that the product is already being produced by other manufacturers, and other factors. One example of how the program’s aggressive schedule is driving risk is the risk related to the steel cut strategy for the molding tools. Plastic components for medical devices often have strict dimensional requirements with very limited allowable variation [27]. The plastic components for the CGM Program are produced using injection molding. In order for the plastic components to meet dimensional variation requirements, the dimensions of the mold cavities (typically made from steel) must be very precise. A typical strategy when making mold cavity tools is to cut them slightly smaller,
produce a test run of parts to evaluate the dimensional performance, and to make micro-
adjustments, called “steel cuts”, to the mold cavities based on the results [28]. To shorten the
molding validation timeline, and since the molding tools being made were duplicates of those
being used at another production facility, Flex and the customer agreed to validate some of the
molding tools without any allowance for steel cuts.

The risk event itself is that if the molding tools produce parts that do not meet dimensional
capability requirements, the tools may require significant rework or have to be remade entirely—
a process which can take months. The schedule limitations for the CGM Program, among other
factors, drove decision-makers to try to save time in the planned schedule at the expense of even
greater schedule delays if something went wrong. While an aggressive project timeline has
potential benefits, such as avoiding procrastination, it is difficult to measure the added risk of
such a strategy. However, a prerequisite to measuring the risk added by aggressive schedules is
having robust processes to identify and analyze the potential impact of uncertainty in schedule
estimates. Assessing whether the aggressive schedule is a driver for individual project risks is a
way to highlight that these processes are necessary and to quantify the overall impact on program
risk at the project planning phase.

6.3.2. Cross-functional Dynamics

As described in Chapter 3, the CGM Program team structure is divided into several functional
areas. The primary functional areas are Automation, Sterilization, Facilities, Surface Mount
Technology (SMT), Conveyor, Molding, IT, and Quality Systems. Each functional area is
assigned its own PM, technical lead, and supporting team. Due to the cross-functional nature of
many of the program activities, it is essential that the different functional areas are able to
communicate and coordinate with one another effectively. This condition can be a risk driver, as
is the case for a risk related to the ownership of IT system validation described below:

A “System Owner” is responsible for validation of IT system. [In the case of one
particular IT system], the “System Owner” is both the Automation Engineer and
Validation Engineer. These resources may not have the bandwidth to support IT
validation since they are already very busy supporting automation validation
activities.
The risk event itself is about whether the current resource loading for the project provides enough capacity for the team members to execute tasks on time; however, complex cross-functional dynamics are contributing to the overall uncertainty. The IT systems are developed by the IT team, while the validation procedures are developed by the Quality Systems team. An Automation Engineer, on the Automation team, is responsible for executing the task in question, but first needs to be trained by both the IT team and Quality Systems team. No single team has the authority to overrule the priority of other teams, and coordinating decision-making between them adds time to the process and puts the schedule at additional risk.

Figure 40 shows a breakdown of the risks tagged with the Cross-Functional Dynamics risk driver and also the total number of risks for each functional area. IT has the highest proportion of cross-functional risks to total risks, indicating that IT activities have an impact on many different functions. Facilities also has a high proportion of cross-functional risks, likely a result of the need for construction to be completed before other functional areas can begin work. One interesting observation is that although Automation has the second highest number of total risks, only two cross-functional risks fall under Automation. This may be due to the fact that at the time of this evaluation, most of the Automation activities were still occurring at the equipment supplier site. It is also notable that all of the cross-functional risks owned by Molding are related to Automation (Figure 41) and they have the most overlap out of all of the functional areas. The functional area pairs with the 2nd highest level of overlap, Facilities and Sterilization, Quality and Facilities, and IT and Validation, all have some sort of shared management. It may make sense for the CGM Program leads to assign a person to be responsible for coordination between Molding and Automation as well.
Risks by Functional Area Owner

Figure 40. CGM Program cross-functional and total risks categorized by functional area.

Risk Linkages between Functional Areas

Figure 41. Risk linkages between functional areas.
6.3.3. Customer Knowledge Transfer

In the case of the CGM Program, transferring knowledge from the customer has been particularly important in order to relay learnings from existing production of the product at other factories to Flex. However, the exchange of information between any contract manufacturer and their customer is often critical to the success of any production development project. The following risk event is an example of how this can drive uncertainty for the CGM Program:

The capacity for the SMT line is based on bill of material assumptions. The takt/cycle time may be affected if component requirements are changed by the customer.

There is inherent uncertainty wherever an assumption is made, but here the level of uncertainty is exacerbated by the fact that the assumption was made based on both the knowledge of the Flex team and the knowledge of the customer. Because of imperfect information sharing between Flex and the customer, Flex may not fully understand the likelihood of changes to the component requirements or the assumptions that the original bill of materials is based on. By quantifying how the knowledge shared by the customer is affecting the overall risk level of the program, Flex can reinforce the need for open communication and identify areas that may require additional input or clarification from the customer.

6.3.4. Lack of Technical Experience

Expertise and experience, particularly a lack thereof, is associated with a reduced ability to identify and assess risk. The collective ability of a team to identify and address project risks can be improved by increasing the average level of expertise and experience of the group [29]. Without proper risk management discipline, risks are often defined simply as “Process X is new to Company Y” as means to try to articulate that unknown risks may arise. It can be argued that a lack of expertise and experience can be better classified as a risk driver than a risk. The following is an example of a risk associated with the Lack of Expertise risk driver from the CGM Program:

Conveyor maintenance technicians may not be fully trained in-time to be able to keep machines running smoothly during production ramp, may extend production stops and schedule delays.
The risk event itself is about whether technicians will be hired and trained in time to operate the conveyors properly during production ramp, but one of the conditions driving this risk is that advanced conveyor technology is new to this particular Flex site. The site needs to hire technicians, but it also does not have anyone with technical expertise in this area to train them. Since Flex has not ramped up conveyors of this scale at this site before, there is more uncertainty around the amount of time and resources that will be required to avoid problems at ramp. To bridge this gap, Flex can leverage the conveyor expertise at some of its other factories or the conveyor supplier.

The team members, technologies, and processes for each functional area were reviewed by the Lead Program Manager for the CGM Program to identify which were new to the CGM Program team, the factory site, Flex overall, and the industry overall. The table used can be found in Appendix 4. This data is plotted in a bubble chart (Figure 42), with the ratio of new technologies and processes to total technologies and processes on the x-axis and the ratio of new team members to total team members on the y-axis. The size of the bubbles is proportional to the total number of new team members, technologies, and processes. Sterilization has the highest ratio of new technical aspects, which is consistent with the fact that this program is the first time Flex has developed an in-house sterilization process. SMT and Molding are core competencies for Flex overall and the factory site, respectively, so it follows that they would have relatively low ratios of new technologies and processes; however, it is notable that the ratio of new team members to the site, Flex, and industry is relatively high since many new people were hired to meet the human resources needs of the CGM Program.
6.4. Implications for Flex

The insights derived from this analysis can be used to inform decision-making during planning and execution of the production development phase, as well as to identify potential gaps. The risk drivers related to having Aggressive Schedule and Lack of Technical Expertise can more effectively influence decisions during the planning phase when the program schedule is established, and when resources are allocated. If the program’s schedule is determined early on to have the potential to drive risky behavior, this factor can be incorporated into schedule negotiations and modifications. If the program is determined to have high ratios of new people, processes, and tools in certain functional areas, targeted action can be taken to reassess the risks associated with these functional areas. If it is determined that the lack of technical experience may elevate risk, additional training or expert internal or external resources can be added to reduce overall risk. Cross-functional Dynamics and Customer Knowledge Transfer are risk drivers that may be identified during the planning phase but may not be apparent at first or may change over the course of the program. These risk drivers can highlight the need for more
effective communication and collaboration between internal functional areas or between Flex and their customer.

These insights can also be applied to inform the development of new metrics and risk monitoring systems at Flex. For example, an evaluation checklist similar to the one shown in Appendix 4 could be used to evaluate the technical expertise of the team at the start of a new project and identify potential gaps and areas to be monitored. The level of knowledge transfer from the customer that will be necessary could also be evaluated at the start of a project by using a checklist format. Over the course of a project, changes in the environmental conditions may require the risk drivers to be reassessed in order to identify emerging risk drivers. The SHIELD tool could be used to integrate the risk driver monitoring process into overall risk management activities. SHIELD could also be used to record and update the status of key risk drivers. While additional work is required to explore how risk driver management could be integrated into the risk management process, this analysis shows more broadly that risk driver analysis may be useful to help Flex more proactively manage risks.

6.5. Chapter Summary

In this chapter, the top 5 risk drivers for the CGM Program are analyzed to derive concrete insights into the conditions that are indirectly creating a heightened state of risk for the program. The top 5 risk drivers include an aggressive program schedule, highly-cross functional dynamics, significant required knowledge-transfer from the customer, and a lack of technical expertise. The results of this analysis address the research questions related to project risk management frameworks and risk management culture posed by the thesis. They establish that frameworks, specifically the Risk Driver model, can be used to inform decision-making for key stakeholders. Additionally, it is possible to infer from the results that by developing more structured ways to address and manage risks, Flex leadership will be able to more effectively identify and communicate risk management priorities.
7 Conclusions

7.1. Review

7.1.1. Frameworks

This work has presented several frameworks that supplement the establishment of risk management practices. One common factor across all of the frameworks is structures that enable users to differentiate between risks and issues. These frameworks emphasize the key underlying distinction—the presence of uncertainty—which reinforces the fundamental concept that a risk is the effect of uncertainty on outcomes. Another characteristic that these frameworks have in common is that they are simple. The concepts that they present are not particularly complicated, but the simplicity focuses the framework on basic principles. These frameworks facilitate proactive risk management if they are integrated into a robust overarching risk management process.

7.1.2. Pilot Implementation

The primary interventions made to improve risk management practices during the pilot implementation include introducing a “Champion” for risk management, training workshops, and a new risk tracking tool. The “Champion” effectively intervened to help the team overcome adoption barriers but cannot sustain improved practices in the long-term. By partnering with CGM Program team leaders early in the process, a shared sense of ownership of the risk management practices was developed. Although the problem statement originally framed risk management as a cultural problem for Flex, none of the interventions directly change culture. Instead, structured ways to establish a risk management process and address risks were created. Further investigation is required to determine whether these structures, in addition to the necessary buy-in from key risk management stakeholders, are sufficient to drive cultural change.

7.1.3. Risk Drivers

The application of the Risk Driver framework to an in-depth analysis of the CGM Program risks confirms that risks share common drivers. By identifying and analyzing these drivers, this information can be used to inform decision-making in order to develop interventions that have
the broadest possible impact. Additionally, these insights can be used to identify new metrics and evaluation systems that may help Flex better understand the overall risk level of a program. This analysis also shows that useful insights can be derived from risk drivers without knowing the outcome of the risk event.

7.2. Future Work

7.2.1. Assigning a “Champion” to Future Change Management Projects

It is clear from the results that having a “Champion” for risk management helped establish improved risk management practices both by helping to overcome adoption barriers and by inherently signaling the priority level of risk management from the perspective of management. As such, there is an opportunity for Flex to explore whether this model can be applied to accelerate behavioral change on other projects, whether they are related to risk management or other areas. Flex could continue to investigate the effectiveness of this type of intervention either as part of future internship projects or by incorporating it into a full-time role.

7.2.2. Incorporate Frameworks into Tools

Flex’s long-term objective is to implement project risk management improvements on all ongoing programs within HRS and other branches of the company. In order to accomplish this as efficiently and effectively as possible, Flex should leverage standardized tools that are already in-use across the company to communicate best practices. The recommended platforms for implementation are the online program management tool SHIELD and online training.

*Incorporate Frameworks into SHIELD*

The SHIELD online program management tool is utilized by all programs in the HRS group. By incorporating frameworks, processes, and other supplementary resources into the tool, Flex can maximize their access to individual behavior as quickly as possible. One example of how this has already been done is by integrating an Issue Log into the SHIELD Risk Register. Each time a user enters a new risk (or issue), they are forced to select from a drop-down menu to assign it either as a “Risk” or “Issue.” The “Issue or Risk” field in the SHIELD Risk Register is shown in Figure 43. This minor feature inherently drives the user to think about whether the event they are
concerned about is an issue or a risk, and subsequently what differentiates them. Incorporating more features like this into SHIELD and other tools can encourage best practices.

![SHIELD tool risk register with “Issue or Risk” column added](image)

**Integrate Training Programs**

Flex has a variety of ongoing initiatives related to risk management, but many of them do not address fundamental concepts. In order to develop robust and consistent risk management practices across the company, Flex should integrate risk management training into one cohesive module and include training on fundamental principles. By leveraging some of its existing online training platforms, such as PM Prime, Flex can quickly deploy improved training standards to many employees at once.

### 7.2.3. Validate Risk Driver Analysis

There is also an opportunity for future work to study the application of the Risk Driver framework in practical application. While risks were analyzed using the Risk Driver framework as part of this research, there was not an opportunity to apply the insights gained from the analysis to decision-making in practice and evaluate the impact on results. Insights regarding Risk Drivers may be generalizable across companies and industries, which increases the potential for broad benefit.
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8 Bibliography


### Appendix 1: Flex Risk Register Template

<table>
<thead>
<tr>
<th>Risk ID</th>
<th>Risk Event</th>
<th>Probability</th>
<th>Impact</th>
<th>Priority</th>
<th>Owner</th>
<th>Workstream</th>
<th>Risk Response Planning</th>
<th>Status Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Change in assumption on product A</td>
<td>High</td>
<td>Medium</td>
<td>High</td>
<td>Early</td>
<td>Jm</td>
<td>Automation Change in production plan</td>
<td>Acceptable</td>
</tr>
<tr>
<td>2</td>
<td>Incorrect assessment of technical complexity on module per agreed with customer</td>
<td>High</td>
<td>Medium</td>
<td>High</td>
<td>Regular</td>
<td>Bob Molding</td>
<td>Replace wth Supplier</td>
<td>Unresolved</td>
</tr>
<tr>
<td>3</td>
<td>Supplier supplier delivery schedule scope creep of task Y</td>
<td>Medium</td>
<td>High</td>
<td>Medium</td>
<td>Late</td>
<td>Mary Sterilization</td>
<td>Recurring item in each status review</td>
<td>Resolved</td>
</tr>
<tr>
<td>4</td>
<td>Inflation of Material X paid in WEB</td>
<td>Low</td>
<td>Medium</td>
<td>Low</td>
<td>Late</td>
<td>PM</td>
<td>Change in production plan</td>
<td>Resolved</td>
</tr>
</tbody>
</table>
Appendix 2: Workshop 1 Evaluation Survey Questions

Libre Risk Workshop 1 Feedback Survey

Start of Block: Default Question Block

Q13 This survey is strictly voluntary and anonymous. RESPONSES ARE CONFIDENTIAL. Please note that responses may be used in aggregate for research purposes and to provide feedback to enhance Flex's risk management.

Q1 1) What was your confidence in the team’s ability to identify and manage the Libre program risks prior to the risk workshop?

○ 1 (not at all confident) (1)
○ 2 (2)
○ 3 (3)
○ 4 (4)
○ 5 (very confident) (5)

Q3 2) What was your confidence in the team’s ability to identify and manage the Libre program risks after the risk workshop?

○ 1 (not at all confident) (1)
○ 2 (2)
○ 3 (3)
○ 4 (4)
○ 5 (very confident) (5)
Q2 3) Rate your understanding of the risk management process for Libre before the workshop.

- 1 (little to no understanding) (1)
- 2 (2)
- 3 (3)
- 4 (4)
- 5 (full understanding of the process and how to execute) (5)

Q4 4) Rate your understanding of the risk management process for Libre after the workshop.

- 1 (little to no understanding) (1)
- 2 (2)
- 3 (3)
- 4 (4)
- 5 (full understanding of the process and how to execute) (5)

Q5 5) Did the workshop help clarify the roles and responsibilities for Risk Management?

- Strongly disagree (1)
- Somewhat disagree (2)
- Neither agree nor disagree (3)
- Somewhat agree (4)
- Strongly agree (5)
Q11 6) Do you feel like this workshop was a valuable use of your/the team's time?

- Strongly disagree (1)
- Somewhat disagree (2)
- Neither agree nor disagree (3)
- Somewhat agree (4)
- Strongly agree (5)

Q7 7) Do you have any comments about how the workshop went?

____________________
____________________
____________________
____________________
____________________

Q10 8) What questions do you still have?

____________________
____________________
____________________
____________________
____________________

End of Block: Default Question Block
Appendix 3: Pilot Study Final Evaluation Survey Questions

Libre Risk Project Final Feedback Survey

Q1 This survey is strictly voluntary and anonymous. RESPONSES ARE CONFIDENTIAL. Please note that responses may be used in aggregate for research purposes and to provide feedback to enhance Flex's risk management practices.

Q2 What is your role on the Libre program?

- PM role (1)
- Non-PM role (2)

Display This Question:

If What is your role on the Libre program? = PM role

Q3 How many years of experience do you have doing project risk management?

- No prior experience (1)
- <1 year (2)
- 1-3 years (3)
- 3-5 years (4)
- 5+ years (5)
Q5 Rate your confidence in your ability to do the following:

<table>
<thead>
<tr>
<th></th>
<th>Extremely confident (1)</th>
<th>Very confident (2)</th>
<th>Somewhat confident (3)</th>
<th>Little confidence (4)</th>
<th>Not at all confident (5)</th>
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<tbody>
<tr>
<td>Identify new program risks (1)</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<td>0</td>
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<tr>
<td>Differentiate between a risk and an issue (2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Give a risk rating that is consistent with the team's rating standard (3)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Determine an appropriate risk response (4)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Use SHIELD to track risks (5)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Q8 Rate your understanding of the following:

<table>
<thead>
<tr>
<th>Full understanding (1)</th>
<th>Fair understanding (2)</th>
<th>Some understanding (3)</th>
<th>Little understanding (4)</th>
<th>No understanding (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Libre team's roles and responsibilities for risk management (1)</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Libre risk management process (2)</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Libre risk management metrics (3)</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>The value of risk management to the Libre program (4)</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

Q7 The risk workshops in July and August helped improve your understanding of risk management practices and expectations for Libre.

- ○ Strongly agree (1)
- ○ Somewhat agree (2)
- ○ Neither agree nor disagree (3)
- ○ Somewhat disagree (4)
- ○ Strongly disagree (5)
- ○ I did not attend the workshops (6)
Q10 The Libre team was able to sustain the risk management practices presented in the workshops.

- Strongly agree (1)
- Somewhat agree (2)
- Neither agree nor disagree (3)
- Somewhat disagree (4)
- Strongly disagree (5)
- I did not attend the workshops (6)

Display This Question:

If What is your role on the Libre program? = PM role

Q11 What tool(s) do you use to track and manage risks?

- SHIELD (1)
- Excel or other tools (2)
- Mix of SHIELD and other tools (3)
- Do not use a risk register (4)

Display This Question:

If What is your role on the Libre program? = PM role
Q12 On average, how often do you review risks with your team?

- 2 or more times per week (1)
- Once per week (2)
- Once every 2 weeks (3)
- Once a month (4)
- Less than once a month (5)

Q15 The Libre risk management process is an effective channel to communicate and escalate potential risks and issues.

- Strongly agree (1)
- Somewhat agree (2)
- Neither agree nor disagree (3)
- Somewhat disagree (4)
- Strongly disagree (5)
Q23 Would additional resources, such as another workshop session, 1:1 mentoring, or online training, would help improve your understanding of project risk management?

______________________________________________________________________

______________________________________________________________________

______________________________________________________________________

______________________________________________________________________

______________________________________________________________________

Q24 Please provide any questions or comments you have (i.e. about risk management practices, SHIELD tool, or the approach to implement risk management improvements on Libre)

______________________________________________________________________

______________________________________________________________________

______________________________________________________________________

______________________________________________________________________

______________________________________________________________________

End of Block: Default Question Block
# Appendix 4: Risk Driver Definitions

<table>
<thead>
<tr>
<th>Risk Driver</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aggressive Schedule</td>
<td>A condition in which the project timeline is truncated to the point that program managers operate under the assumption that there is no buffer in the critical path of the schedule.</td>
</tr>
<tr>
<td>Cross-Functional Dynamics</td>
<td>An environment in which one or more cross-functional areas are highly dependent on one another for information, materials, or support in order to execute tasks.</td>
</tr>
<tr>
<td>Documentation Requirements &amp; Standards</td>
<td>A condition in which required documentation and standards either do not exist or the existing documentation does not meet standards.</td>
</tr>
<tr>
<td>Knowledge Transfer from Customer</td>
<td>An environment in which the stakeholders are highly dependent on the customer for information.</td>
</tr>
<tr>
<td>Lack of Technical/Medical Expertise</td>
<td>A condition in which a technical aspect of the project is new to the team, the site, the company, or the industry.</td>
</tr>
<tr>
<td>Production System Complexity</td>
<td>A system of production that is highly complex with respect to the number of process steps involved, the technical difficulty of the different process steps, and the level of interconnectedness between steps.</td>
</tr>
<tr>
<td>Product Complexity/Requirements</td>
<td>A product that is highly complex with respect to the number of parts, the technical difficulty of producing the dimensional specifications, the variety and complexity of materials used, and/or the innovativeness of the design.</td>
</tr>
<tr>
<td>Lack of Centralized Ownership</td>
<td>An environment in which ownership of tasks, workstreams, or areas is not clearly established and understood by the key stakeholders involved.</td>
</tr>
<tr>
<td>Scope Increase</td>
<td>A change in the project scope that increases the number of tasks or amount of work needed to execute the project.</td>
</tr>
<tr>
<td>Medical Regulatory</td>
<td>An environment that includes products, processes, and/or infrastructure that is approved, controlled, and monitored by a medical regulatory body.</td>
</tr>
<tr>
<td>Supplier Capability/Capacity</td>
<td>A condition in which unknown or undefined limits in supplier capability and/or capacity can drive risk downstream.</td>
</tr>
<tr>
<td>New Site</td>
<td>An environment in which the facility, employees, and infrastructure are new to the company and/or recently established.</td>
</tr>
<tr>
<td>Complex Machine Integration</td>
<td>A condition in which the process of integrating individual machines into the overall system/to one another is highly complex.</td>
</tr>
<tr>
<td><strong>Limited Floor Space</strong></td>
<td>An environment in which the available factory floor space is a significant constraint on the design and construction of the overall production system</td>
</tr>
<tr>
<td>------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Insufficient Human Resources</strong></td>
<td>A condition in which there are not enough human resources assigned to reasonably complete the tasks assigned to them within the allotted time period.</td>
</tr>
<tr>
<td><strong>Multiple Suppliers</strong></td>
<td>A condition in which having multiple suppliers for the same or different, interrelated components and or/equipment drive significant complexity</td>
</tr>
<tr>
<td><strong>Complex Supply Chain Logistics</strong></td>
<td>A condition in which the logistics of transferring components and equipment through the supply chain is complicated by distance, number of steps, suppliers, and/or extreme conditions.</td>
</tr>
<tr>
<td><strong>Labor Market Challenges</strong></td>
<td>A condition defined by uncertainty and volatility in the labor market</td>
</tr>
<tr>
<td><strong>Component Market Volatility</strong></td>
<td>A condition in which the market for a particular component (or equipment) is highly volatile</td>
</tr>
</tbody>
</table>
## Appendix 5: Experience Assessment Sample Chart

<table>
<thead>
<tr>
<th>Item</th>
<th>Team</th>
<th>Site</th>
<th>Flex</th>
<th>Industry</th>
</tr>
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